

TriService Nursing Research Program: Fast Track Award Program Announcement

I. How to Use This Document

This Program Announcement document contains specific information and instructions for the TriService Nursing Research Program (TSNRP) Fast Track Award. General information and instructions for all grants are located in the Application Instructions. Follow both the instructions contained in this document as well as those in the Application Instructions when preparing and submitting your grant application.

II. Overview of the Fast Track Award

Purpose

The purpose of the Fast Track Award is to support military-relevant and military-unique research that:

- Investigates an emerging threat, time-sensitive question(s), or Service-directed question(s) regarding military nursing clinical practice, education, management, and/or policy that directly relates to the research priorities and strategic goals of TSNRP.
- Aligns with the applicant's interest and capability.

Award Amount

You may request funding 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.

III. Eligibility

Active duty, Reserve, and National Guard military nurses who **either**:

- Have completed at least one extramurally funded research study post-dissertation.
- Are currently conducting an extramurally funded research study post-dissertation.
- Were the first author on at least two original data-based publications that report post-dissertation research in a refereed scholarly journal(s).

The Fast Track Award is particularly appropriate for:

- Experienced investigators who have the capability and resources to rapidly design and conduct a research study on an emerging threat, time-sensitive research question, or Service-directed research question.
- Experienced nurse scientists who propose to conduct research while deployed.

IV. Timeline

Grant Application Submission

You may submit your Fast Track Award grant application on any day between the first Tuesday in October and June 1. Applicants are encouraged to apply early in the fiscal year because funding is subject to availability of funds.

Review and Funding Decisions

Scientific and programmatic review of the grant application begins on the first day of the month after it arrives in the TSNRP office. TSNRP's goal is to provide a funding decision within 12–15 weeks after it receives the grant application.

V. Required Forms and Documents

Include each of the following forms and documents in your grant application. Instructions for completing the forms and other required pieces of your grant application are included in [Section VI](#) of this Program Announcement.

Cover Letter from Applicant Organization

Obtain a signed cover letter from the Applicant Organization of your choice and attach it to the original copy of your grant application. This letter should be on the Applicant Organization's letterhead and should include:

- The title of your proposed study.
- The TSNRP Call for Proposals year, written as “FY201x” (where x denotes the last digit of the year).
- Your complete contact information.
- The name and contact information of your Applicant Organization.



See Section V of the Application Instructions for more information on Applicant Organizations.

TSNRP Grant Application Cover Packet

Include the TSNRP Grant Application Cover Packet at the beginning of each copy of your grant application. You can find this packet on the [TSNRP Grant Application Forms](#) Web page.

Relevance to Military Nursing Form

The last page of the TSNRP Grant Application Cover Packet is the Relevance to Military Nursing Form. Each copy of your grant application should include this form as well.

PHS 398 Forms

These [forms](#), part of the Public Health Service (PHS)'s grant applications, are used for TSNRP grant applications as well. Be sure to follow TSNRP instructions for each form (given in the following section) rather than the PHS 398 instructions, which may not be the same. You do not need to submit any PHS 398 forms that are not listed here.

- [Form Page 1: Face Page](#)
- [Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells](#)
- [Form Page 3: Research Grant Table of Contents](#)
- [Form Page 4: Detailed Budget for Initial Budget Period, Direct Costs Only](#)
- [Form Page 5: Budget for Entire Proposed Project Period, Direct Costs Only](#) (Note: You will use this form to detail your budget justification.)
- [Biographical Sketch Format Page](#)
- [Resources Format Page](#)
- [Continuation Format Page](#) (Note: You will use this form to write your Research Plan.)
- [Checklist Form Page](#)



The PHS 398 forms have been revised several times. Be certain that you are using the most current version by using only the forms in MS Word format linked from this Program Announcement.

Your grant application may also include several [appendices](#), which do not need to be submitted on any particular form.

VI. Instructions for Completing the Grant Application

When application instructions differ, information contained within this Program Announcement supersedes instructions on the forms themselves.

General Instructions

Type your name (Last, First, Middle) in the header of each page following the Face Page.

TSNRP Grant Application Cover Packet

Complete all sections of this cover packet in full as indicated on the form. You may, but are not required to, add a one-page letter with any information unique to your situation that you wish to



See Section VIII of the Application Instructions for general instructions on preparing and formatting your grant application.

communicate to the TSNRP Executive Director, members of the Scientific Review Panel, or the Advisory Council.

Relevance to Military Nursing Form

This form is on the last page of the TSNRP Grant Application Cover Packet. In the box provided, write an abstract that describes in full how the research study you are proposing addresses an emerging threat, time-sensitive question, or Service-directed question that directly relates to the research priorities of TSNRP. Carefully consider the [purpose](#) of the Fast Track Award mechanism; do not use it merely to circumvent the application deadline for another grant award mechanism.



The relevance abstract that you will write on the Relevance to Military Nursing Form is **military specific** and is different from the research abstract that you will write on the PHS 398 Form Page 2. The abstract must clearly and succinctly describe how the research qualifies for a Fast Track Award.

Form Page 1: Face Page

Box 1: Title

Select a title that is specific and appropriate to your proposed research topic. The title should be no more than 81 characters long, including spaces.

Box 2: Response to Specific Request...

- Check the box indicating “YES.”
- *Number:* N/A.
- *Title:* TriService Nursing Research Program.

Box 3a: Name

Fill in your name as indicated on the form.

Box 3b: Degrees

Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., RN).

Box 3c: Position Title

List your current title in your organization.

Box 3d: Mailing Address

Provide the complete information necessary for postal delivery, including your room number, building, street address, and ZIP code.

Box 3e: Department

Specify the department you belong to in your organization.

Box 3f: Major Subdivision

Identify your subdivision or subdepartment, if applicable.

Box 3g: Telephone and Fax Numbers

Provide your daytime telephone number and fax number, if available.

Box 4: Human Subjects Research



See [45 CFR 46.102](#) and [21 CFR 50.3](#) for the Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) definitions of human subjects research.

Check the box indicating “Yes” if you plan to conduct any activities involving human subjects at any time during the proposed study period, **even if** your research is exempt from regulations for the protection of human subjects.

Check the box indicating “No” if you do not plan any activities involving human subjects at any time during the proposed study period.

Box 4a: Research Exempt

Check the box indicating “Yes” if all your proposed research activities are exempt from the human subjects research regulations.

If you checked “Yes,” specify your exemption number. Your exemption number corresponds to one of six [exemption categories](#).



Only the research performance site Institutional Review Board (IRB) can determine if your research is exempt; you cannot make this determination. Nonetheless, those who evaluate the grant application may find this information useful. See the instructions for the [Research Plan](#) for more information about TSNRP IRB requirements.

Box 4b: Federal-Wide Assurance No.

If your Applicant Organization has a current Federalwide Assurance (FWA) on file with the Office of Human Research Protection (OHRP), enter the number in the space provided.

Box 4c: Clinical Trial

Check the appropriate box to indicate whether your proposed research study is a clinical trial. A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (e.g., drugs, treatments, or devices or new ways of using known drugs, treatments, or devices).

Box 4d: NIH-Defined Phase III Clinical Trial

Check the box indicating “Yes” if your proposed research study is a clinical trial and:

- Is a broadly based prospective clinical investigation, possibly involving several hundred or more human subjects.
- Evaluates an experimental intervention in comparison with a standard or controlled intervention or compares two or more existing treatments.
- Aims to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

Box 5: Vertebrate Animals

Check the box indicating “Yes” if you plan any research activities involving vertebrate animals at any time during the proposed study period.

Box 5a: Animal Welfare Assurance No.

If your Applicant Organization has a current, approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), enter its number here. If you have other performance sites or collaborating institutions, do not include their Animal Welfare Assurance Numbers.

Box 6: Dates of Proposed Period of Support

Enter the beginning and end dates of the TSNRP funding that you are requesting, as indicated on the form.

Box 7a: Direct Costs (\$)

Enter the “Total Direct Costs for Initial Budget Period” from “Form Page 4: Detailed Budget for Initial Budget Period” in this space.

Box 7b: Total Costs (\$)

Enter the sum of: (1) the “Total Direct Costs for Initial Budget Period” from “Form Page 4: Detailed Budget for Initial Budget Period” and (2) the Facilities and Administrative Costs (F&A)/Indirect Costs for the “initial budget period,” as calculated in #3a on the “Checklist Form Page.”

Box 8a: Direct Costs (\$)

Enter the “Total Direct Costs for Entire Proposed Project Period” from “Form Page 5: Budget for Entire Proposed Project Period.”


Box 8b: Total Costs (\$)

Enter the sum of: (1) “Total Direct Costs for Entire Proposed Project Period” from “Form Page 5: Budget for Entire Proposed Project Period” and (2) the “Total F&A Costs” for all years, as calculated in #3 on the “Checklist Form Page.”

Note that the “Total Direct Costs” used to calculate this item includes any consortium F&A costs.

Box 9: Applicant Organization

Enter the name and address of your Applicant Organization. This organization will be legally and financially responsible for the conduct of activities supported by your award.

 You must have an Applicant Organization to receive a TSNRP award. This organization must be a nonprofit organization, such as a university. See Section V of the Application Instructions for more information.

Box 10: Type of Organization

Check the box indicating the type of organization that best describes your Applicant Organization. Your Applicant Organization may not be a for-profit organization.

Box 11: Entity Identification Number, DUNS Number, Congressional District

Enter each of these numbers for your Applicant Organization.

Box 12: Administrative Official to Be Notified If Award Is Made

Name the official at your Applicant Organization who TSNRP will notify in the event that you are awarded a Fast Track Award. Include the person’s complete address for postal delivery, telephone number, fax number, and email address, as indicated.


Box 13: Official Signing for Applicant Organization

Provide the complete name and contact information for the institutional official who will sign this form. This individual must have formal designation or delegated authority to sign on behalf of the organization.

Box 14: Applicant Organization Certification and Acceptance

Ask the official named in Box 13 to sign and date in Box 14.

By signing the grant application’s Form Page 1: Face Page, the Authorized Organizational Representative of the Applicant Organization certifies that the organization will comply with all applicable policies, assurances, or certifications referenced in your grant application.

 See Section VI of the Application Instructions for more information on policies, assurances, and certifications.

The Applicant Organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in your grant application, including the F&A rate. Deliberate withholding, falsification, or misrepresentation of information could result in such administrative actions as withdrawal of a grant application, suspension or termination of an award, or debarment of individuals as well as possible criminal penalties.

The signer further certifies that the Applicant Organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported study resulting from your grant application. The Applicant Organization may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the research.



Submit the original copy of your application (with original ink signatures) to TSNRP.

Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells

Use this form to describe the study you are proposing, your study sites, and the people on your research team.

Project Summary

Use this section to write your research abstract. Your research abstract should:

- Succinctly and accurately describe the research you are proposing.
- Provide a complete overview of the entire research study to a reader who does not read the rest of your grant application.
- State the broad long-term objectives of the proposed study.
- State the specific aims of the proposed study.
- Briefly describe the proposed research design, rationale, and methods for achieving your study's objectives and aims.



The research abstract you write on Form Page 2 is different from the relevance abstract you write on the [Relevance to Military Nursing Form](#). The research abstract will discuss only the research you propose to conduct, without the emphasis on your study's impact on military nursing.

Relevance

In two or three sentences, describe how your proposed research is relevant to the body of nursing science.

Project/Performance Site(s)

List each site where you will perform the work for your proposed research study. Depending on your study, you may have more than one performance site, which may not necessarily be your assigned duty station.



On the [Resources Format Page](#), you will justify your choice of performance site(s).



Do not fill in your performance site(s) DUNS number(s). **Do** provide all other requested information.

Scientific/Key Personnel

Scientific/key personnel are people who:

- Contribute substantively to the scientific development or execution of the study.
- Devote measurable effort to the study, not occasional or as-needed effort.



People who provide technical services, such as transcription, are not scientific/key personnel.



TSNRP does not allow co-PIs. You will be the only PI on your study, though you may include associate investigators (AIs).

List yourself on the first line of scientific/key personnel, because you are the Principal Investigator (PI) of the study. List all other scientific/key personnel after you in alphabetical order by last name. Provide all requested information for each individual. ERA Commons information is not necessary.

Other Significant Contributors

In this section list the names, affiliations, and roles of any individuals who have committed to contributing to the scientific development or execution of your study but who will not commit any specified measurable effort to it. These individuals might include an assistant who provides a small amount of help for recruiting subjects to the study or a consultant who spends minimal effort on the study.



You will provide biographical sketches for all scientific/key personnel and other significant contributors on the [Biographical Sketch Format Page](#).

Human Embryonic Stem Cells

Indicate if your proposed research will use human embryonic stem cells by checking the appropriate box. If you indicated “Yes,” list each cell line that will be used according to the instructions on the form.

Form Page 3: Research Grant Table of Contents

Complete the table of contents with the correct page numbers for the sections that apply to your grant application.

Check the box indicating that you have an appendix. In the space below the checkbox, list each appendix and its contents. For example:

Appendix I: Instruments XYZ
Appendix II: Survey
Appendix III: Publications

Form Page 4: Detailed Budget for Initial Budget Period, Direct Costs Only

Use this form to detail the **direct costs** on which you will spend your grant award money during the first year of your grant.



Direct costs do not include F&A costs.

The budget you list on this form must be:

- Complete.
- Accurate.
- Total \$150,000 or less per year in direct costs.
- Reasonable.



Common Budget Items for Fast Track Awardees

This list contains many items that TSNRP grantees often include in their budgets; however, it is not exhaustive or prescriptive:

- Computer equipment and software.
- Specialized training courses (e.g., training course for ATLAS.ti software).
- Postage (e.g., to mail surveys or to ship specimens).
- Laboratory/medical equipment.
- Laboratory/medical supplies.
- Analysis of laboratory specimens (e.g., complete blood count).
- Use of a copyrighted research instrument (e.g., the Beck Depression Inventory).
- Office supplies.
- Travel to research sites.
- Patient care costs.
- Transcriptionist for qualitative data.
- Conference attendance (including travel and registration fee) to disseminate research findings (U.S. only).
- Poster preparation and printing.
- Manuscript preparation, including editorial support.
- Research animals, animal care supplies, and animal care fees.
- Consultant (e.g., statistician) fees.
- Research assistant salaries.
- Project director salary.
- AIs' salaries.

Personnel

In this section, list each person involved in your proposed research 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.



Include another nurse scientist who has agreed to continue the research in the event that you are away for more than 3 months. Include a letter of support from this person as an appendix to your application.

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.

Ignore the heading “Inst. Base Salary” for active duty and Federal employees. Instead, use this column to specify the time on station, projected permanent change of station/assignment date, or end of time in service for all military personnel on your research team to demonstrate the last date at which they will be able to participate directly in your study. Under “Inst. Base Salary,” enter the salaries for any personnel on the study who are neither Federal employees nor active duty military personnel.



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, list their salary as “WOC” (without compensation).

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.



List “WOC” (without compensation) for each consultant involved in your research who is on active duty or is a Federal employee.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants other than those 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.



You will describe each consultant's services in the [Budget Justification](#) on Form Page 5.

Equipment

List each item of equipment that you will purchase with the award and its cost. List each item and cost separately.

Supplies

List each category of supplies that you will purchase with the award along with the total cost for the category if the category total is less than \$1,000. If the total is greater than \$1,000, list each item and cost in that category individually.

If you are requesting research animals, list the species and the number of each.



Computer and Software Requests

- The maximum allowable cost for computer equipment and software is \$3,000.
- Some Applicant Organizations consider computers and software to be equipment; other Applicant Organizations consider them to be supplies. Check with your Applicant Organization on which classification to use on your grant application.
- Any computer equipment or software that you request should be based on the needs of the research you propose and should be well justified.

Travel

List each travel request and travel cost separately. This travel should be necessary for the completion or dissemination of the research you propose. You may only include *domestic* dissemination-related travel.

For each travel request and for each individual, list:

- The purpose of the travel.
- The potential destination.
- Estimated round-trip airfare or car mileage.



A maximum of \$2,000 per award may be budgeted for travel to scientific conferences or meetings for the purpose of research dissemination within the U.S. Note that dissemination activities typically occur in the last year of the proposed research.

- Estimated hotel prices.
- Estimated per diem costs.
- The registration fee, if applicable.

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

Inpatient Care Costs/Outpatient Care Costs

Itemize patient participation costs in your proposed research study. These costs may only be patient care costs associated with participation in your study.

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).



You may request no more than \$500 for the preparation of dissemination materials.



TSNRP awards do not pay for Cooperative Research and Development Agreement (CRADA) or IRB fees.

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



In general, your budget may not include incentives for research participation. However, if you have a unique need to provide monetary reimbursement to participants in your study, contact the TSNRP Director, who will consider requests on a case-by-case basis.

Consortium/Contractual Costs

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including F&A costs. Contractual costs for support services, such as the 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).

For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional budget page(s) after Form Page 5, numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)



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 AI who will be in charge of the study at his or her site. Under the agreement, you must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific percent of effort from the consortium organization’s lead AI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. Provide the details of any consortium/contractual arrangements in your [Research Plan](#).

Form Page 5: Budget for Entire Proposed Project Period, Direct Costs Only

Complete this table with your requested budget items for the entire period of your proposed study as well as the subtotals and totals requested. The first column, “Initial Budget Period,” will contain the information you entered in Form Page 4.

Justification

In this space, and on extra pages if needed, justify your request for:

- Each budget item on Form Pages 4 and 5.
- The inclusion of each individual listed on the study. Describe each individual’s specific function. This includes 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.
- 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. 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.

Biographical Sketch Format Page

Page limit for this section: Four pages for each person.

Include a biographical sketch for each person you listed as Key Personnel or Other Significant Contributors, in the order in which you listed them on Form Page 2. Complete the education block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution, the degree received (if applicable), the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency. ERA Commons information is not necessary.

For each individual, create a biographical sketch that includes the following four parts:

- Personal statement.** Briefly describe why the individual's experience and qualifications make him or her particularly well-suited for the role (e.g., PI, project manager) in the study proposed in your grant application.
- Positions and honors.** List previous positions in chronological order, concluding with the present position. List any honors. Include present membership on any Federal government public advisory committee and any military assignments.
- Peer-reviewed publications or manuscripts in press.** Limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. You may choose to include selected publications based on recency, importance to the field, or relevance to the proposed research. When citing articles that fall under the Public Access Policy, provide the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article, if available. For articles that are not covered by the Public Access Policy but are publicly available in a free, online format, you may include URLs or PMCID numbers along with the full reference citation (note that copies of



More information on the Public Access Policy can be found at <http://publicaccess.nih.gov/>.

publicly available publications are not acceptable as appendix material).

- D. **Research support.** List both selected ongoing and completed research studies for the past 3 years. Begin with the studies that are most relevant to the research proposed in the grant application. Briefly indicate the overall goals of the studies and the responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

This part defines each individual's scientific expertise and emphasizes his or her professional accomplishments. Reviewers will use this information to assess each individual's qualifications for his or her designated role on the study and the overall qualifications of the research team.

Resources Format Page

Use this page to describe the resources at each performance site that are available for your proposed research. Reviewers will use this information to assess the capability of the organizational resources available to perform your study.

Identify the facilities that you and your collaborators will use (e.g., laboratory, clinical, animal, computer, office). If appropriate, indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the study. Describe only those resources that are **directly applicable** to your proposed research.

Provide any information describing the Other Resources available to your study (e.g., machine shop, electronic shop) and the extent to which they would be available.

Describe how the scientific environment in which you will conduct the research contributes to the probability of success (e.g., institutional support, physical resources, intellectual rapport). In describing this environment, discuss ways in which your proposed study will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

Describe your Applicant Organization's investment in your success as an 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 your 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 [Research Plan](#).)

Continuation Format Page (Research Plan)

Page limit for this section: 12 pages total for items 3–5 (below), which includes any figures or tables. (Some items have their own page limits, as indicated below.)

Use this form to write your **Research Plan**. Your Research Plan will contain the following sections:

1. *For resubmitted or revised grant applications only:*
Introduction. Also include the “Recommendations and Revisions for FY__ Submission” form here. Use this form to respond to reviewer comments on your previously submitted grant application.
2. Specific Aims. (If you are not resubmitting a revised grant application, this item will be the first in your Research Plan.)
3. Background and Significance.
4. Preliminary Studies/Progress Report.
5. Research Design and Methods.
6. Bibliography and References Cited/Progress Report Publications List.
7. Protection of Human Subjects.
8. Inclusion of Children.
9. Vertebrate Animals.
10. Consortium/Contractual Arrangements.



See the Application Instructions, Section X, for more information on resubmission.

Specific Aims

Page limit for this item: One page.

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

The Specific Aims should:

- Be easy to read and be presented logically.
- Suggest the relevance of the study that you propose to TSNRP’s mission.
- Refer to the current state of knowledge in your area of study, noting how the proposed study will fill gaps in that knowledge.
- Indicate the expected outcomes of the study and the expected impact of the study findings.

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 that identifies gaps that your proposed study intends to fill.
- Describe the effect of the studies you cite on the concepts, methods, technologies, treatments, services, and interventions that form the basis of your proposed study.
- State how your study will advance scientific knowledge or clinical practice if the study aims are achieved.
- Include any economic impact that you expect the research findings to have.



It is your scientific and scholarly responsibility to cite and give specific credit for other authors' work. However, another author's *opinion* does not provide adequate support for your work; therefore, include only fact-based citations.

Remember to include all cited reference in the bibliography.

Preliminary Studies/Progress Report

Highlight preliminary work your research team has done in the proposed area of study. This demonstrates that your team has mastered the technical aspects of the proposed research, including accessing the proposed sample population and pilot testing the proposed instruments.

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

Be sure to:

- Include relevant data from unpublished research.
- Describe what your preliminary data show and why the findings are significant to the proposed research.
- Report only research by members of your proposed research team.



You can place any relevant **published** preliminary research that supports your proposed study in an appendix to your grant application if necessary.

Research Design and Methods



The research design and methods you propose should logically follow from the specific aims of your research, as described by your Research Plan. Organize the Research Design and Methods section carefully to make this connection obvious to reviewers.

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 make clear what will be done, how it will be done, who will do it, and how data will be interpreted, fully describing every step

in 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.



[Letters of support](#) for your access to places and populations needed for your study are critical to the success of your grant application. Include these letters in an appendix.

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.

Dissemination plan. Explain the strategies that you will use to disseminate the results of your research study.



TSNRP expects all grantees to publish the results of their research in a peer-reviewed journal. Posters or presentations at national meetings—such as military medicine, clinical, or policy meetings—are also good ways to disseminate your research results.

Bibliography and References Cited

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.

Provide the PMC reference number (e.g., PMCID234567) for each citation that falls under the National Institutes of Health (NIH) Public Access Policy. You may include URLs or PMCID numbers along with the full reference for citations that are not covered by the Public Access Policy but that are publicly available in a free, online format.



Make sure that all references in the text appear in the bibliography in the same sequence in which they appear in the text.

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.



Include a draft of your **informed consent document** in the appendix. It must contain the following under the section labeled “Confidentiality”: “The Institutional Review Board of [the specified study site]; the Uniformed Services University of the Health Sciences, Bethesda, MD; and other Federal agencies that provide oversight for human subject protection may see your records.”

Consult the current 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.

IRBs. 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 performance site(s) IRB(s). Note that 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.



Refer to Section XIII of the Application Instructions for helpful references regarding human subjects protection.

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 that only an IRB can determine if your research is exempt from human subjects regulations.

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 you include.
- The appropriateness of the available facilities to accommodate the children.
- The inclusion of a sufficient number of children to allow for 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.

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). 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.
- 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 the conduct of your research.
- A description of the use of analgesic, anesthetic, and tranquilizing drugs or comfortable restraining devices, where 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 on Euthanasia. If the method does not accord with the guidelines, justify your choice of the euthanasia procedure.

Institutional Animal Care and Use Committees (IACUCs). If you receive a TSNRP Investigator-Initiated Award, the IACUC at each of your research and performance sites 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.



Refer to Section XIII of the Application Instructions for helpful references regarding study animal protection.

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. See the instructions for Form Page 4, [Consortium/Contractual Costs](#), for more information on Consortium/Contractual Arrangements.

Checklist Form Page

Type of Application

Check each box that applies to your grant application. (Check the box labeled “NEW application” if you are submitting this application to TSNRP for the first time.)

Program Income

Indicate here in the format requested the amount of gross income your Applicant Organization expects to earn that is directly generated by a supported activity or earned as a result of this award. If the amount is zero, state “none.”



Examples of Program Income

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing.
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds.
- Third-party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity.
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.
- Patent or copyright royalties (exempt from reporting requirements).
- Registration fees generated from grant-supported conferences.

See the [NIH Grants Policy Statement](#) for a more detailed explanation of program income.

Assurances and Certifications



See Section VI of the Application Instructions for more information on assurances and certifications.

This section ensures that your Applicant Organization's authorized representative (who signed Form Page 1: Face Page of your grant application) agrees to comply with any policies, assurances, or certifications required by your proposed study.

Facilities and Administrative Costs (F&A)/Indirect Costs

If you are requesting funding for F&A costs, check the appropriate box indicating the rate agreement your Applicant Organization has negotiated (is negotiating) and provide the date on which the agreement was established, if applicable.

Calculate your F&A costs for the initial and all future budget periods using the formulae provided. The "rate applied" is the current negotiated F&A rate minus exclusions. You do not need to list the exclusions on the checklist or anywhere in your grant application. However, both the F&A rate and the direct cost base used to calculate the F&A costs must be included for each year.

The indirect cost rate itemized by your Applicant Organization on the Checklist Form Page should correspond to the rate on the budget pages and the Face Page of your grant application.

Appendices

Include one set of appendices with each copy of your grant application.

Include in an appendix any 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.
- The use of any instruments not in the public domain requires the **authors' permission**. If you are using any such instrument, include letters from the authors or their legal representatives granting permission to you 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.
- Letters of support and any other letters (see below).
- Timeline (see below).



Don't use your appendix to circumvent the page limits of the Research Plan. Except when indicated otherwise, include any graphs, diagrams, tables, or charts in the body of the Research Plan, not in the appendix.

Letters of Support

Include original, signed 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.)
- **AIs.**
- **Consultants.** These letters should include the scope of the consultants' work and responsibilities, level of commitment and percentage effort, and duration of the commitment.
- **Site commanders** (if relevant).
- **Commander, chief nurse, director, supervisor, Service-specific nursing research specialty consultant, Corps Chief, Surgeon General, and/or other leader who recommends or supports use of the Fast Track Award mechanism.**

Timeline

Provide a detailed timeline that delineates how your research 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 that if you plan to study vulnerable populations or use multiple performance sites, IRB processing will be slowed. See the [sample timeline](#) for an example.



See Sections VIII and IX of the Application Instructions for information on formatting and submitting your completed grant application.

VII. Grant Application Evaluation

All grant applications undergo a two-tiered review process:

- Scientific merit review, conducted by experienced nurse scientists.
- Programmatic review, conducted by members of the Advisory Council.

These reviews' outcomes guide the final funding decisions made by TSNRP's Executive Board of Directors.

Throughout the review and decision process, confidentiality and conflict-of-interest measures are enforced.

Scientific Merit Review

The scientific merit review is a *criteria*-based process by which at least two experienced nurse scientists evaluate and score the grant application. TSNRP selects nurse scientists from the nursing and health care communities based on their research expertise, professional experience, and publication history, ensuring that the scientists have no actual, apparent, or potential conflict of interest with the grant application. The nurse scientists evaluate and score each grant application for scientific and technical merit, independent of any other grant applications under consideration. In addition, a military nurse scientist from one of the three uniformed Services will review the grant application.

Scientific Merit Review Procedures

For each grant application, TSNRP staff designates one nurse scientist as *primary reviewer* and one nurse scientist as *secondary reviewer*. In some cases, a third nurse scientist may be asked to review and score the grant application. These individuals evaluate the science of the proposed study by reviewing, scoring, and preparing evaluative comments of the grant application.

The military reviewers evaluate the grant application and prepare evaluative comments; however, they do not score the grant application. They provide valuable insight and comments that:

- Augment the other reviewers’ evaluation regarding the feasibility of conducting the proposed research.
- Address military relevance of the proposed study.
- Address the stability of the research team.

Scoring

Reviewers score grant applications on a scale of 0–9 (in whole number intervals), with the exception of grant applications submitted in the wrong funding category (see below).

The scientific review scoring scale is as follows:

Score	Descriptor	Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses
0	Zero Score	Fails to meet established standards and formatting
--	No Score	Submitted in the wrong funding category
<p>Minor Weaknesses: An easily addressable weakness that does not substantially lessen impact.</p> <p>Moderate Weakness: A weakness that lessens impact.</p> <p>Major Weakness: A weakness that severely lessens impact.</p>		

A grant application receives a “Zero Score” when it fails to meet established standards as determined by both the primary and secondary reviewers. Grant applications that receive a “Zero Score” will not receive a subsequent programmatic review. A grant application receives a “No Score” when it meets established standards but was submitted in the wrong funding category. Grant applications receiving a “No Score” will continue through the scientific and programmatic review process.

Reviewer Discussion

If the scores or evaluative comments of the primary and secondary reviewer differ substantially, the Executive Director may request that the reviewers discuss the application during a teleconference call.

Scientific Merit Review Criteria

Primary and secondary reviewers evaluate the merit of grant applications using the following criteria:

- **Six core review criteria.** Feedback from reviewers on these criteria allows the applicant to identify reasons for the grant application's score and to improve or strengthen the grant application on a potential resubmission.
 1. **Scientific approach and technical merit.** This criterion is crucial because it assesses:
 - The research design. This includes: purpose, theoretical framework or model, research questions or hypotheses, research method, definitions, study population and sampling strategy, research procedures, intervention protocol (if applicable), feasibility, adequacy of the approach, measures, data management and analysis plan, timeline, limitations, and dissemination plan.
 - Whether the overall strategy, methodology, and analyses are well reasoned and appropriate to accomplish the specific aims of the research.

If any part of the research study does not merit support, the reviewer may recommend its deletion and a corresponding adjustment to the budget.

Reviewers note whether the application is revised from a previously submitted TSNRP grant application. For resubmissions, reviewers comment on how the applicant addressed feedback from a previous scientific and programmatic review(s), improvements, and any remaining weaknesses.

2. **Qualifications, expertise, and research experience of the PI and research team.** This criterion evaluates all key personnel's training and record of accomplishments. Reviewers note the following for each key individual: name, degree, title, field of training or experience, publication record, and whether the PI and team are well suited to conduct the research. Reviewers also note any missing expertise that is required to complete the research.

3. **Originality and innovative nature of the grant application; applicability of previous findings.** This criterion assesses:
 - The originality of the nursing research problem. This includes the use of new concepts, approaches, or methods in the proposed research.
 - The innovation in translation or application of previous findings to solve nursing or health care problems.
 4. **Significance and relevance to nursing research.** This criterion evaluates the proposed study's potential contribution to nursing and the importance of the research problem it addresses. Reviewers:
 - Comment on whether the proposed study addresses an emerging threat, a time-sensitive question(s), or a Service-directed question(s) that directly relates to the research priorities of the TSNRP.
 - Discuss whether successful completion of the proposed study's aims will change the concepts, methods, technologies, treatments, services, or preventive interventions that propel nursing research.
 - Address the strengths and weaknesses of the grant application.
 - Consider the potential for the study to solve a nursing or health care problem.
 5. **Availability of institutional resources and adequacy of the environment to support the study.** This criterion assesses the appropriateness and adequacy of the environment for the proposed research; the quality and extent of institutional support; and the availability and accessibility to facilities and equipment, such as clinics, inpatient units, the vivarium, office or laboratory space, conference rooms, computers, and the library. In addition, personnel factors are considered, including the opportunity to interact with other scientists and knowledgeable colleagues and the quality and value of collaborative arrangements.
 6. **Protection of human and animal subjects.** This criterion evaluates the risks to subjects, the adequacy of protection against these risks, the potential benefits to the subjects and others, the importance of the knowledge to be gained, and the data and safety monitoring plan.
- **Budget and research duration.** This additional review criterion assesses the reasonableness of the budget and proposed study duration. Reviewers provide specific recommendations and rationale for any budget modifications they make. Similarly, reviewers make specific recommendations regarding study duration.

Military reviewers evaluate the merit of grant applications using the following criteria:

1. **Military feasibility.** This criterion assesses the likelihood that the military research team will achieve the goal of the research. Reviewers address the accessibility to the proposed population, the feasibility of recruiting and retaining the proposed sample, institutional support for the research, and the adequacy of the environment and resources where the research will be conducted.
2. **Military relevance.** This criterion evaluates the potential contribution of the proposed research to military nursing, the importance of the research problem to military health care, and the extent to which the research addresses an emerging threat, a time-sensitive question(s), or a Service-directed question(s) that directly relates to the research priorities of the TSNRP.
3. **Stability of the research team.** This criterion evaluates the research team's ability to carry out the study as proposed. Reviewers assess whether the research team includes built-in redundancy or overlap of roles and expertise; this would help to compensate for any team members' move to a new duty location, temporary duty assignment to another location, or deployment. In addition, reviewers note any type of military expertise required for the research that is missing.

All reviewers address the following:

1. **Level of enthusiasm.** Reviewers rate their level of enthusiasm for the proposed study as high, moderate, or low.
2. **Title of the grant application.** Reviewers evaluate how well the title of the grant application reflects the actual grant application and categorize as a good match, partial match, or poor match.

Reviewers' Comments

Reviewers' written evaluations are key documents that provide the rationale for their recommendations and score. TSNRP provides all applicants with an unedited copy of the reviewers' written evaluations to provide feedback on the strengths and weaknesses of their grant applications. In addition, the TSNRP Advisory Council uses the document as it conducts the programmatic review (second-tier review) of the grant application, scores each grant application, and makes a funding recommendation to the Executive Board of Directors.

Programmatic Review

The programmatic review is both a *criteria-* and *comparison-*based process in which the TSNRP Advisory Council evaluates grant applications on their relevance to the TSNRP portfolio. The TSNRP Advisory Council consists of one active duty and one Reserve member from each Service.

Programmatic Review Process

Advisory Council members review portions of the grant applications and the outcomes of the scientific merit review. During the programmatic review, the primary and secondary reviewers present their evaluative comments and score to all members of the Advisory Council. The entire council agrees on a final score.

Scores are on a scale of 0–9 (in whole numbers). The scoring scale is as follows:

Score	Descriptor	Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses
0	Zero Score	Fails to meet established standards and formatting
--	No Score	Submitted in the wrong funding category
<p>Minor Weaknesses: An easily addressable weakness that does not substantially lessen impact.</p> <p>Moderate Weakness: A weakness that lessens impact.</p> <p>Major Weakness: A weakness that severely lessens impact.</p>		

Programmatic Review Criteria

- Scientific merit.
- Military relevance and uniqueness.
- Extent to which the proposed research addresses an emerging threat, time-sensitive question, or Service-directed question regarding military nursing clinical practice, education, management, and/or policy that directly relates to the research priorities and strategic goals of the TSNRP.
- Strengths and stability of the research team.
- Potential benefit of the proposed research relative to the proposed budget.
- The applicant’s education and military experience.
- Performance history (applicants who have received a previous grant award from TSNRP).

Previously Funded PIs

In the event that the applicant received a previous TSNRP award, the Advisory Council will also evaluate the applicant's past performance history as a TSNRP grantee during the programmatic review. The Advisory Council will consider:

- The applicant's compliance with Federal, USU, and TSNRP requirements, such as timely submission of IRB approval documents, progress reports, final reports, and other items specified by the study's terms and conditions.
- The applicant's efforts to disseminate TSNRP-funded research findings in peer-reviewed journals and at scientific conferences.



TSNRP expects timely publication of research findings in peer-reviewed journals.

Funding Decisions

The TSNRP Executive Board of Directors makes final funding decisions based on:

- The mission, research priorities, and goals of TSNRP.
- Outcomes of the scientific merit and programmatic reviews.
- Recommendations of the Advisory Council.



The Executive Board of Directors' funding decisions are final and cannot be appealed.

The Executive Board of Directors is composed of the Assistant Surgeon General, Medical Force Development and Assistant Surgeon General, Nursing Services (U.S. Air Force); the Chief, U.S. Army Nurse Corps; and the Director, U.S. Navy Nurse Corps.

Appendix 1. Sample Timeline

The sample below was created for a study employing survey and focus group methodology. You should create timelines that are specific to your proposed research. Be sure to identify the calendar year in addition to the study year. Place your timeline in an [appendix](#) where indicated.

	YEAR 1 (2009)				YEAR 2 (2010)			
	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Jul-Sep
Recruit & Hire Study Personnel	■							
Print Questionnaires & Create Database	■							
Establish Liaison with Units		■						
Prepare Questionnaire Mailing		■						
Send 1 st Mailing of Questionnaires			■					
Send Reminder Postcards			■					
Send 2 nd Mailing of Questionnaires			■					
Obtain APFT Results & Enter in Database			■					
Scan Questionnaire into Database			■					
Questionnaire Data Cleaning					■			
Questionnaire & APFT Data Analysis					■			
Data Interpretation					■			
Focus Group Training and Planning					■			
Focus Groups						■		
Focus Group Data Interpretation						■		
Identify Intervention Strategies to Increase Exercise Participation								■
Report & Manuscript Preparation					■			■

Adapted from timeline provided courtesy of COL (Ret.) Laura R. Brosch, ANC.

Appendix 2. Exemptions from Department of Health and Human Services Human Subject Protections

The six categories of research exempt from the HHS human subjects regulations are:

Exemption 1

Research conducted in established or commonly accepted educational settings involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.



Exemption 2 for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see [45 CFR Part 46, Subpart D](#)), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Exemption 3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

The [human subjects regulations decision charts](#) of the Office for Human Research Protection (OHRP) will determine whether the research falls under the human subjects regulations and if so, whether it meets the criteria for Exemption 4. The [NIH Office of Extramural Research Web site](#)

also contains information that is helpful for determining whether human subjects research meets the criteria for Exemption 4.

Exemption 5

Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6

Taste and food quality evaluation and consumer acceptance studies: (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.