DEPARTMENT OF DEFENSE

FISCAL YEAR 2002
NATIONAL PRION RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT

August 1, 2002

Headquarters, U.S. Army Medical Research and Materiel Command
MCMR-PLF, 1077 Patchel Street
Fort Detrick, Maryland 21702-5024

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Foreword

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed to establish the Department of Defense (DOD) National Prion Research Program (NPRP). The deadline, format, and other criteria specified for proposals in this DOD Fiscal Year 2002 (FY02) NPRP Program Announcement are based on program objectives, public needs, and regulatory guidance.

Specific information on the USAMRMC, U.S. Army Medical Research Acquisition Activity, the Congressionally Directed Medical Research Programs (CDMRP), and the DOD NPRP can be obtained from the CDMRP web site at http://cdmrp.army.mil. A copy of this program announcement and associated forms also can be downloaded from the CDMRP web site; hard copies of the program announcement will not be provided.

1. Who May Apply

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply through an eligible institution. Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. Please refer to sections on individual award mechanisms for additional eligibility criteria.

2. Submission Deadline

An electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, must be uploaded/submitted through the Internet at http://cdmrp.org/proposals by an authorized Administrative Representative of the Sponsored Programs Office (or equivalent) of your organization no later than **11:59 p.m. (applicant's local time) October 30, 2002**. See Appendix B, part 21, and Appendix C for additional details.

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

3. Timeline

Letter of Intent:	All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than September 30, 2002. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02nprp1
Proposal Receipt Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet at http://cdmrp.org/proposals no later than **11:59 p.m. (applicant's local time) October 30, 2002**
Peer Review:	December 2002
Request for RCQ[1] Documents:	As early as January 2003
Programmatic Review:	February 2003
Notification:	Approximately 2 weeks after programmatic review
Award Date:	**Between March 2003 and September 2003**

4. Inquiries

Questions concerning the **proposal format or required documentation** can be addressed to the CDMRP at:

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (NPRP02-Program Announcement)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

Applicants should submit questions regarding this program as early as possible. Every effort will be made to answer questions within 5 working days.

5. Proposal Submission

Applicants should refer to sections on individual award mechanisms and Appendix B for appropriate submission requirements.

[1] Regulatory Compliance and Quality

Proposals will be submitted electronically at http://cdmrp.org/proposals. An authorized Administrative Representative from the Sponsored Programs Office of the applicant's organization must upload/submit one electronic PDF version of the applicant's proposal, which will count as the official proposal submission.

Several steps are critical for successful electronic submission of the applicant's proposal.

1. The applicant is required to submit Proposal Information at http://cdmrp.org/proposals, to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf (see Appendix C). **The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process at least 2 weeks prior to the submission deadline.**

2. Once the applicant has submitted the Proposal Information to http://cdmrp.org/proposals, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that a proposal submission has been initiated.

3. After the Proposal Information has been submitted, applicants will need to provide the Administrative Representative with an electronic copy of the proposal. Please ensure that the content of the PDF file is representative of your complete submission. Applicants are encouraged to coordinate early with their Sponsored Programs Office.

4. The Administrative Representative is required to provide final approval of the Proposal Information and then to upload/submit the proposal file in PDF. Please note that the web site does not allow applicants to upload/submit their proposals directly. **Proposals may ONLY be uploaded/submitted by the Administrative Representative from the Sponsored Programs Office (or equivalent) and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. The Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the web site (http://cdmrp.org/proposals) no later than **11:59 p.m. (applicant's local time) October 30, 2002.** Detailed instructions for electronic submissions can be found at http://cdmrp.org/proposals.

Help lines are also available to answer specific questions regarding the preparation of proposals for **electronic submission or the electronic submission process**. The help line phone number is 301-466-6495. Help can also be obtained by e-mail at help-proposals-cdmrp@cdmrp.org.

I. Overview of the Congressionally Directed Medical Research Programs

I-A. History of the Congressionally Directed Medical Research Programs

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies for peer reviewed research directed toward specific diseases. Beginning in fiscal year 1992 (FY92), the U.S. Congress has directed the DOD to manage these various extra- and intramural grant programs. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, the USAMRMC CDMRP has received more than $2.2 billion targeted by Congress for peer reviewed research on breast cancer, prostate cancer, ovarian cancer, chronic myelogenous leukemia, neurofibromatosis, prion disease, and other specified areas.

The CDMRP exists to support research that will positively impact the health of all Americans. The CDMRP strives to identify gaps in funding and provide opportunities that will enhance program research objectives without duplicating existing funding. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that addresses individual program objectives.

I-B. Investment Strategy

For each program, the CDMRP has developed and refined a flexible execution and management cycle that spans the development of an investment strategy through the completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to the program, establish an appropriate investment strategy, and perform programmatic review as described in Section I-C.2. Based upon this investment strategy, each program then uses a variety of award mechanisms to address the most urgent needs of the research community.

I-C. Proposal Evaluation

The CDMRP uses a two-tiered review process for proposal evaluation as recommended by the National Academy of Science's Institute of Medicine (IOM). The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on program goals.

I-C.1. Scientific Peer Review

Scientific peer review is conducted by panels organized by scientific discipline or specialty area. The primary responsibility of the scientific peer review panels is to provide unbiased, expert advice on the scientific and technical merit of proposals, based upon the review criteria published in the program announcement.

Scientific peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their varied levels of experience with scientific peer review. For the breast, prostate, and ovarian cancer research programs, consumer reviewers are cancer survivors and representatives of consumer advocacy organizations. For the neurofibromatosis research program, consumer reviewers are individuals with neurofibromatosis or their family members and representatives of consumer advocacy organizations. For the National Prion Research Program, consumer input will be solicited as part of an independent IOM study commissioned by the CDMRP. Consumers augment the scientific peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see Section III-B, IV-C, V-B, and VI-B). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at scientific peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the investigator's structured technical abstract and lay (nontechnical) abstract (verbatim), the peer review scores, and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement. Summary statements are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. One of the functions of programmatic review is to select a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members use the peer review

summary statements, which include the proposal abstracts, to review proposals. The Statement of Work may also be reviewed at this level. However, the full proposal is not forwarded to programmatic review.

The IP is committed to funding a broad-based research portfolio. The ratings and evaluations of scientific peer review panels are primary factors in programmatic review; the IP also must consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Military relevance;
- Relative innovation; and
- Program portfolio balance with respect to research disciplines or specialty areas.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

I-D. Notification

Following completion of the two-tiered evaluation process, every applicant will receive notification indicating the award status of his or her proposal, along with the peer review summary statement. Notifications will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

I-E. Negotiation of the Award

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving the U.S. Army Medical Research Acquisition Activity (USAMRAA) and Regulatory Compliance and Quality (RCQ). A Contract Specialist from USAMRAA will contact the administrative representative who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.

Please note that the award start date will be determined during the negotiation process.

Concurrent with the USAMRAA negotiations, RCQ will review the environmental compliance, safety plan, animal use, and human subjects/anatomical substance use documents to ensure that Army regulations are met. The Certificate of Environmental Compliance and Principal

Investigator Safety Program Assurance documents are part of the proposal submission. The Facility Safety Plan (if needed), Research Involving Animals, and Research Involving Human Subjects and/or Anatomical Substances documents will be requested in the applicant's notification and will be reviewed by RCQ staff. All documents related to RCQ will be available through the CDMRP web site (http://cdmrp.army.mil).

I-F. Human Use Requirements Unique to DOD-Funded Research

Important distinctions exist for research funded by the DOD that involves human subjects. In addition to local Institutional Review Board approval to conduct research involving human subjects, a second DOD review and approval are also required. The Human Subjects Research Review Board (HSRRB), administered by the USAMRMC RCQ Office, is responsible for conducting this second level of review. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. **All research protocols involving human subjects and/or anatomical substances must be approved by both the appropriate local review board and by the HSRRB before awards are made and prior to initiation of the research protocol.**

Two requirements specific to DOD-funded research that the applicant must clearly address, if applicable, in the development of a research proposal for submission to the DOD are outlined below.

- Medical Care for Research-Related Injuries. For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, part 7 for more details.

- Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative. Therefore, the applicant should articulate how the research will benefit minors or other individuals that are not legally competent to consent and are part of the placebo arm of the study.

More information regarding research involving human subjects can be found in the RCQ document, "Research Involving Human Subjects and/or Anatomical Substances," which will be available through the CDMRP web site (http://cdmrp.army.mil).

I-G. Annual and Final Reports

All awards will require the timely delivery of several reports during the research effort. These reports are necessary for the CDMRP to monitor progress and evaluate program outcomes.

The Principal Investigator (PI) should plan on a reporting requirement consisting of:

- An **annual** report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and
- A **final** report (submitted in the last year of the award period) that details the findings and issues for the entire project.

I-H. Publications and Patents

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. For example, "This research, under award number DAMD…, was supported by the Department of Defense National Prion Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." PIs must submit a copy of any manuscript or publication resulting from research funded under the award to the CDMRP.

In accordance with the Bayh-Dole Act (35 USC 200 et seq.[1]), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

[1]Title 35, United States Code, Section 200 et seq.

II. Department of Defense National Prion Research Program

II-A. History of the National Prion Research Program

The Department of Defense (DOD) National Prion Research Program (NPRP) is being established in fiscal year 2002 (FY02) to promote research in transmissible spongiform encephalopathies (TSEs), in accordance with the directives received from Congress. The DOD is using the model established through recommendations from the Institute of Medicine to establish the NPRP. The NPRP will employ a two-tiered scientific review process consisting of scientific (peer) review and programmatic review. Congress appropriated $42.5 million for the NPRP in FY02.

II-B. Overview of the FY02 NPRP

The priority goal of the NPRP is to develop antemortem diagnostic tests for TSEs. Proposals will be requested for Idea Awards, Investigator-Initiated Research Awards (with optional Nested Postdoctoral Traineeships), Career Transition Awards, and Prion Techniques Fellowship Awards. In addition, Resource Development Contracts will provide support for developing experimental materials from relevant animal models of TSE disease. Resource Development Contracts will be solicited under a separate announcement. Proposals are encouraged from investigators working at Historically Black Colleges and Universities/Minority Institutions.

Reference Table of Award Mechanisms

The table below summarizes key elements of the award mechanisms offered by the FY02 NPRP. Refer to Sections III-VI for further details and proposal preparation instructions. Please note that the proposal submission deadline is **11:59 p.m. (applicant's local time) October 30, 2002.**

Award Mechanism	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available	Instructions for Proposal Preparation
Idea Awards	All levels of experience	• Reward innovative ideas and technology • No preliminary data required	$375K[1] for direct costs over a 3-year performance period, plus indirect costs as appropriate	Section III
Investigator-Initiated Research Awards (with optional Nested Postdoctoral Traineeship[s])	Independent investigators at any level *Nested Postdoctoral Trainees:* Recent doctoral graduates with 3 years or less of postdoctoral experience	• Sponsor basic and clinically oriented TSE research • Preliminary data required • Encourage development of partnerships between academic and industry researchers or between an established TSE researcher and a researcher from another discipline to leverage diverse expertise and resources toward development of antemortem diagnostics	Maximum of $2.5M[2], inclusive of direct and indirect costs, for a performance period of up to 5 years *Nested Postdoctoral Traineeships:* Maximum of $60K per year inclusive of direct and indirect costs for a maximum of $180K per trainee over 3 years	Section IV
Career Transition Awards	Postdoctoral fellows	• Encourage scientists or clinicians currently in postdoctoral and/or fellowship training positions to pursue a TSE-related research career	*Postdoctoral fellow (years 1-2):* Average of $60K/ year, inclusive of direct and indirect costs, for a maximum of $120K *Junior faculty (years 3-5):* Average of $100K/year in direct costs, for a maximum of $300K, plus indirect costs as appropriate	Section V
Prion Techniques Fellowship Awards	• Postdoctoral trainees, medical residents, or clinical fellows; or • Researchers with independent program of prion research; or • Researchers with established independent program of research with limited or no experience in prion field	• Offer investigators the opportunity to work in the laboratory of established TSE researchers in order to acquire critical skills or learn new methods relevant to TSE research	Up to $125K for up to 1 year, inclusive of direct and indirect costs	Section VI

[1] K = thousand
[2] M = million

Important note regarding duplicate submissions: Submission of the same research project to the FY02 NPRP under different award mechanisms is **not** allowed, and all such duplicate submissions may be administratively withdrawn. This includes duplicate submissions under different award mechanisms by different Principal Investigators. The Government reserves the right to reject any proposal.

III. Idea Awards

III-A. Idea Awards

The ultimate goal of all research under the National Prion Research Program (NPRP) is to move transmissible spongiform encephalopathy (TSE) knowledge toward the development of an antemortem diagnostic test for TSEs. The intent of Idea Awards is to encourage innovative approaches to studying TSEs. Proposals with an emphasis on chronic wasting disease (CWD) in deer and elk are particularly welcome. This award mechanism is designed to encourage innovative approaches to TSE research from both established TSE investigators and established investigators in other fields who want to move into TSE-related research.

Idea Award proposals should create or introduce a unique or unusual approach to the study of the prevention, treatment, inactivation, or diagnosis of TSEs, especially as they relate to CWD. As a guideline to applicants and reviewers, proposals may be innovative in a variety of ways, including study concept, research methodology or technology, clinical interventions, and adaptation of existing methods or technologies. This list is not all-inclusive, but is intended to serve as a scaffold on which to frame the innovative features of the proposal. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Idea Awards are not intended to continue avenues of research already established. The incremental advancement of a hypothesis, the exploration of a hypothesis in a different cell line, or the use of a published series of in vitro assays to further characterize a model system are examples of aims appropriate for other funding mechanisms. The NPRP anticipates that the submission of truly innovative proposals will result in high impact and may require high risk research.

Although Idea Award proposals do not require preliminary or pilot data, they should be based on a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning. The research strategy will be evaluated based on appropriateness of the design to test the hypothesis, not whether the hypothesis is ultimately proven or disproven. The proposed studies may be untested, but should have a high probability of revealing new avenues of investigation. Although this research is inherently risky in nature, the research plan must demonstrate solid scientific judgment and rationale.

Approximately $5 million will be available for Idea Awards. Funding for Idea Awards can be requested for a maximum of $375,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses (including research supplies), equipment, and travel to scientific/technical meetings.

For complete proposal requirements, please refer to Section III-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections III-B and III-C.

Submission of the same research project to the Fiscal Year 2002 NPRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different Principal Investigators (PIs). The Government reserves the right to reject any proposal.

III-B. Scientific Peer Review Evaluation Criteria for Idea Award Proposals

Scientific peer review will focus on the intent of the Idea Award mechanism to encourage innovative approaches to TSE-related research. Idea Award proposals will be evaluated according to the following criteria:

- **Innovation:** Is the proposed research innovative in study concept or question, research methods or technologies, adaptations of existing methods or technologies, or in other ways? Does the project propose new paradigms, challenge existing paradigms, or address underexplored or unexplored areas?

- **Disease Relevance:** Does the proposal make a convincing case for the relevance of the research toward ultimately developing an antemortem test for TSEs? What will be the effect of these studies on the concepts or methods that will facilitate achieving this goal?

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data? If the research plan requires statistical analysis, is there a clear statistical plan with power analysis included in the proposal? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics?

- **Principal Investigator:** Is the PI appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?

- **Environment:** Is there evidence that the scientific environment is an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?

- **Budget:** Is the budget appropriate for the research proposed?

III-C. Programmatic Review Evaluation Criteria for Idea Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Idea Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

III-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than September 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02nprp1

III-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Idea Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Applicants must submit the Proposal Information at http://cdmrp.org/proposals prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdmrp.org/proposals by **11:59 p.m. (applicant's local time) October 30, 2002.** Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.
   Eligible Idea Award applicants must be independent investigators at any level.

2. Proposal Acceptance Criteria – See Appendix B, part 2.
   Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

3. Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Idea Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to the development of an antemortem test for the detection or diagnosis of TSE-related diseases. Articulate how the combination of innovation and relevance in the proposal will impact and further programmatic goals.

11. Proposal Body – See Appendix B, part 11.
    The body of Idea Award proposals is limited to **10 pages,** inclusive of figures, tables, graphs, and photographs, if used.

    Describe the proposed project using the general outline provided below:

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the specific aims and the research strategy of the study.

    d. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.

    e. Innovation: State concisely how the proposed research uses innovative hypotheses or methods to advance toward the development of an antemortem test for the detection and/or diagnosis or TSEs.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    Note: Signed letter(s) of support from institutions and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Funding for Idea Awards can be requested for a maximum of $375,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, and travel to scientific meetings. The amount allotted for travel is $1,800 per year to attend scientific/technical meetings.

    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, part 7 for more details.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdmrp.org/proposals by **11:59 p.m.**

(applicant's local time) October 30, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues will be available through the CDMRP web site (http://cdrmp.army.mil). See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

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IV. Investigator-Initiated Research Awards (with optional Nested Postdoctoral Traineeship[s])

IV-A. Investigator-Initiated Research Awards

The ultimate goal of all research under the National Prion Research Program (NPRP) is to move the transmissible spongiform encephalopathy (TSE) field toward development of an antemortem diagnostic test for TSEs. The intent of Investigator-Initiated Research Awards (IIRAs) is to sponsor basic and clinically oriented research in TSEs. These grants are intended to fund independent investigators from all academic levels across a broad spectrum of disciplines. The development of **partnerships** that will leverage diverse resources and expertise toward the development of an antemortem diagnostic test for TSEs is strongly encouraged. Such partnerships may be between academic and industry researchers or between an established TSE researcher and a collaborative researcher from another discipline who might bring new technologies and expertise to the TSE field. All IIRA proposals **must include preliminary data** relevant to TSE research and the proposed project. Proposals with military relevance are specifically sought.

The Fiscal Year 2002 (FY02) NPRP encourages investigators to submit IIRA proposals that are designed to:

- Develop a rapid, sensitive, and reproducible test for the detection of prions suitable for use as an antemortem diagnostic test;
- Develop a rapid, sensitive, and reproducible test for the detection of prions suitable for use a screening assay; and/or
- Study the prevention, transmission, inactivation, or pathogenesis of TSEs, to include chronic wasting disease (CWD).

Approximately $20 million will be available for IIRAs. Funding for IIRAs can be requested for a maximum of $2.5 million, inclusive of direct and indirect costs, for a performance period of up to 5 years. The amount allotted for the Principal Investigator (PI) to travel to scientific/technical meetings is $1,800 per year. Institutional support and commitment to foster the applicant's research career, such as the provision of access to adequate animal and laboratory facilities and equipment, must be demonstrated in the proposal.

For complete proposal requirements, please refer to Section IV-F. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-C and IV-D.

Submission of the same research project to the FY02 NPRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms by different PIs. The Government reserves the right to reject any proposal.

IV-B. IIRAs with Nested Postdoctoral Traineeship(s)

Nested Postdoctoral Traineeships are being offered as an optional part of IIRA proposals. The intent of the Nested Postdoctoral Traineeship is to enable doctoral degree graduates to either extend ongoing research related to TSEs or broaden the scope of their research to include work relevant to TSEs under the guidance of a designated mentor who is participating in the proposal. It is expected that the training will provide a valuable opportunity to further develop the experience necessary to advance the trainee's research career in TSEs.

A trainee is defined as a postdoctoral fellow with 3 years or less of postdoctoral experience at the time of proposal submission. Eligible postdoctoral candidates must have successfully defended a doctoral thesis and completed all academic requirements at the time of award negotiations.

There is a limit of three postdoctoral trainees that can be nested within a given IIRA proposal. However, Nested Postdoctoral Traineeships can only be obtained as an optional part of the IIRA mechanism and may not be obtained separately. Support for postdoctoral trainees is in addition to the $2.5 million cap for IIRAs. Applicants must submit a biographical sketch of no more than three pages for each trainee and include it in the biographical sketch section (see Appendix B, part 14). "To be named" trainees are acceptable for the proposal submission. For proposals approved for funding, the U.S. Army Medical Research Acquisition Activity must be provided with the name and biographical sketch of each applicant for review and approval.

For the Nested Postdoctoral Traineeship portion of IIRA proposals, funding can be requested for a maximum of $60,000 per year inclusive of direct and indirect costs for a maximum of $180,000 per trainee over 3 years. Training awards frequently have a lower institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead charges. Direct costs can cover salary, stipends, seminars and courses, expenses including research supplies, equipment, and travel to scientific/technical meetings. Expenses relevant to the traineeship should be listed under the "Other" category on the Detailed Cost Estimate Form (see Appendix B, part 18).

IV-C. Scientific Peer Review Evaluation Criteria for IIRA Proposals

IIRA proposals will be evaluated according to the following criteria:

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Do the required preliminary data in TSE research support the proposed project? Is the experimental design sound and sufficiently well developed with the required statistical power to lead to significant results?

- **Relevance:** Does the proposal make a convincing case for the relevance of the research toward ultimately developing an antemortem diagnostic test for TSEs? Does this study address a critical problem in TSE research? To what extent will the project, if successful, make an original and important contribution to the goal of advancing research in the field?

- **Principal Investigator and Personnel:** Is the PI appropriately trained and well suited to carry out this work? Does the PI show potential for contribution to the TSE field? Is the proposed work appropriate to the experience level of the PI and other researchers or collaborators (if any)? Is appropriate expertise available to conduct the study successfully? **For proposals involving partnerships:** Are the qualifications of the collaborating investigator(s) appropriate? Does the collaboration offer the PI the opportunity to provide [gain] additional experience and training? **For IIRAs with Nested Postdoctoral Traineeship(s):** Are the PI and other scientific personnel well qualified to conduct training for the trainee(s)? Is there a senior staff member who is identified and responsible for the trainee(s)? Is the trainee at an appropriate stage in his or her career for such training, and has the trainee made a commitment to enter the TSE field?

- **Environment:** Is there evidence that the scientific environment is an appropriate setting for the proposed research? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support provided with the proposal? **For proposals involving partnerships:** Is there adequate synergy between the involved institutions/organizations? Is there a clear plan for interaction between partners? Do the institutions/organizations involved in the project strengthen the proposal? **For IIRAs with Nested Postdoctoral Traineeship(s):** Is the research training properly structured and balanced to ensure that the trainee(s) will acquire the knowledge and necessary skills relevant to the area of TSEs being studied?

- **Budget:** Is the budget appropriate for the research proposed?

IV-D. Programmatic Review Evaluation Criteria for IIRA Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the IIRA mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

IV-E. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than September 30, 2002. This form is available on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02nprp1

IV-F. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for IIRAs. Please note that the body of the proposal is limited to **20 pages**, inclusive of figures, tables, graphs, and photographs. For IIRAs that include Nested Postdoctoral Traineeship(s), two additional pages are allowed to describe the training plan. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Applicants must submit the Proposal Information at http://cdmrp.org/proposals prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdmrp.org/proposals no later than **11:59 p.m. (applicant's local time) October 30, 2002.** Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.
   Eligible applicants for Nested Postdoctoral Traineeships are postdoctoral students with 3 years or less of experience at the time of proposal submission. At the time of award negotiations, an applicant must have successfully defended a doctoral thesis and completed all academic requirements.

2. Proposal Acceptance Criteria – See Appendix B, part 2.
   Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

3. Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B – Part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.

11. Proposal Body – See Appendix B, part 11.

    a. IIRA Proposal Body.
    The body of IIRA proposals is limited to **20 pages**, inclusive of figures, tables, graphs, and photographs, if used.

    The inclusion of preliminary data **is required** for IIRA proposals; investigators must submit promising and well-founded preliminary data relevant to TSEs and the proposed project.

    Describe the proposed project using the general outline provided below:

    i. Background: Describe the ideas behind the proposed work and cite relevant literature references. Describe previous experience most pertinent to this proposal.

    ii. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    iii. Objectives: State the specific aims and the research strategy of the study.

    iv. Preliminary Data: Provide pertinent data to support the necessity, feasibility, and potentiality of the proposed project.

    v. Methods: Describe the experimental design and methodology.

    b. Nested Postdoctoral Traineeship Proposal Body.
    The body of the Nested Postdoctoral training plan is limited to **2 pages**. Identify the staff members who are responsible for the trainees. Describe the research training in which the trainees will participate such as research, coursework, laboratory techniques, conferences, and journal clubs.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    Note: Signed letter(s) of support from institutions and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).

18. Detailed Cost Estimate – See Appendix B, part 18.
    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. Funding for IIRAs can be requested for a maximum of $2.5 million, inclusive of direct and indirect costs, for a performance period of up to 5 years. The amount allotted for travel is $1,800 per year for the PI. Funding for Nested Postdoctoral Traineeships can be requested for a maximum of $60,000 per year inclusive of direct and indirect costs for a maximum of $180,000 per trainee over 3 years. Postdoctoral funds are in addition to the $2.5 million maximum for the IIRA. Training awards frequently have a lower institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead charges. The amount allotted for postdoctoral trainee travel is $1,500 per year. Direct costs can cover salary, stipends, seminars and courses, expenses including research supplies, equipment, and travel to scientific/technical meetings. In addition, funding should be requested for a one-time, 2-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, part 7 for more details.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs

Office (or equivalent) through the Internet at http://cdmrp.org/proposals no later than **11:59 p.m. (applicant's local time) October 30, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues will be available through the CDMRP web site (http://cdmrp.army.mil). See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

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V. Career Transition Awards

V-A. Career Transition Awards

The ultimate goal of all research under the National Prion Research Program (NPRP) is to move the transmissible spongiform encephalopathy (TSE) field toward development of an antemortem diagnostic test for TSEs. Career Transition Awards (Transition Awards) are designed to support the last 2 years of a postdoctoral fellowship and up to 3 years of a junior faculty position to encourage the recipient to pursue a prion-related research career. These awards are intended to facilitate career advancements by accommodating the relatively long time that it takes to generate data in prion experimental models. Such awards will provide investigators who are committed to prion research the opportunity to acquire the data and experience to move into their first faculty position and compete for traditional awards later in their careers.

The overall goal of Transition Awards is to prepare individuals for careers in prion research and assist investigators in overcoming the difficulties inherent in the field. Important aspects of these applications include (1) the candidate's qualifications and (2) the mentor and the training environment. Proposals should either extend the candidate's ongoing research related to prions or broaden the scope of his or her research to include work relevant to prions, under the guidance of a designated mentor. The research focus of the proposal should address an issue relevant to the development of antemortem diagnostic tests for TSEs, any aspect of chronic wasting disease (CWD), or the prevention, transmission, and pathogenesis of TSEs.

Proposals should be written and signed by the postdoctoral trainee as the Principal Investigator (PI) and author of the proposal, with appropriate technical direction from the mentor. Award applicants must describe their research project, as well as their career goals in the body of the proposal. For complete proposal requirements, please refer to Section V-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections V-B and V-C.

For the postdoctoral portion of the award (years 1-2), the PI may request an average of $60,000 per year, inclusive of direct and indirect costs, for a maximum of $120,000 over the first 2 years of the project. For the junior faculty portion of the award (years 3-5), the PI may request an average of $100,000 per year in direct costs, for a maximum of $300,000 over 3 years. Indirect costs may be added, as appropriate. Direct costs can cover salary, expenses including research supplies, and travel to scientific/technical meetings. PIs should alert their sponsoring institutions that, because of the intent of the award, award funds may be transferred to another institution at the end of postdoctoral training.

For complete proposal requirements, please refer to Section V-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections V-B and V-C.

Submission of the same research project to the Fiscal Year 2002 NPRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

V-B. Scientific Peer Review Evaluation Criteria for Career Transition Award Proposals

Transition Award proposals will be evaluated according to the following criteria:

- **Candidate:** Do the candidate's previous training, prior research experience, and publication record indicate promising achievements to date? Is there a need for the proposed research experience and training in order for the candidate to develop into an independent prion investigator? Is the applicant appropriately trained and well-suited to carry out the proposed research? Has the candidate demonstrated a personal commitment to pursuing a career in prion research, including an appropriate level of effort on this proposal?

- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the postdoctoral trainee and assist him or her with the transition to independent investigator status? What is the mentor's previous research training experience with doctoral students, fellows, residents, etc.?

- **Research Plan:** Are the conceptual framework, hypotheses, design, methods, and analyses of the research adequately developed and well-integrated for the applicant's research program? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Will the research offer a valuable opportunity to further develop research experience to advance and develop the applicant's independent prion research career?

- **Scientific Impact:** Is the proposed research relevant to any aspect of CWD, or the prevention, transmission, and pathogenesis of TSEs? What will be the effect of these studies on the concepts or methods that will facilitate development of an antemortem diagnostic for TSEs? To what extent will the project, if successful, advance research in the field? To what extent will the project facilitate the transition of the applicant from postdoctoral trainee to an independent new investigator?

- **Budget:** Is the budget appropriate?

V-C. Programmatic Review Evaluation Criteria for Career Transition Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Career Transition Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

V-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than September 30, 2002 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs (CMDRP) web site at http://cdmrp.army.mil/funding/default

V-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Career Transition Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.**

Applicants must submit the Proposal Information at http://cdmrp.org/proposals prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdmrp.org/proposals by **11:59 p.m. (applicant's local time) October 30, 2002.** Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.
   All postdoctoral fellows are eligible.

2. Proposal Acceptance Criteria – See Appendix B, part 2.
   Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

3. Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Transition Award applicants should articulate (within the 1-page limit) how the combination of training value and relevance to any aspect of CWD or the prevention, transmission, and pathogenesis of TSEs will catalyze the applicant's development as an independent prion research investigator.

11. Proposal Body – See Appendix B, part 11.
    The body of Career Transition Award proposals is limited to **10 pages**. Figures, tables, graphs, and photographs, if used, must be included in this section.

    a. Career Development Plans: Describe your career development plan and how the proposed experience and training will promote your transition from postdoctoral trainee to an independent investigator in the area of prion research. Discuss your research plans after the completion of this award.

    b. Description of Research Project: Briefly describe the proposed project using the general outline provided below:

        i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

        ii. Hypothesis/Rationale/Purpose: State the hypothesis that will be tested and the expected results.

        iii. Objectives: State concisely the specific aims of the project.

        iv. Methods: Give details about the experimental design and methodology.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    Note: Signed letter(s) of support from institutions and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    For the postdoctoral portion of the award (years 1-2), the PI may request an average of $60,000 per year, inclusive of direct and indirect costs, for a maximum of $120,000 over the first 2 years of the project. For the junior faculty phase of the award, the PI may request an average of $100,000 per year in direct costs, for a maximum of $300,000 over 3 years. Indirect costs may be added, as appropriate. Direct costs can cover salary and expenses, including research supplies. The amount allotted for travel is $1,800 per year to attend scientific/technical meetings.

    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, part 7 for more details.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdrmp.org/proposals by **11:59 p.m. (applicant's local time) October 30, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues will be available through the CDMRP web site (http://cdmrp.army.mil). See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

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VI. Prion Techniques Fellowship Awards

VI-A. Prion Techniques Fellowship Awards

The ultimate goal of all research under the National Prion Research Program (NPRP) is to move the transmissible spongiform encephalopathy (TSE) field toward development of an antemortem diagnostic test for TSEs. Prion Techniques Fellowship Awards (PTFs) are designed to offer investigators the opportunity to work in the laboratory of an established prion researcher in order to acquire critical skills or learn new methods relevant to prion research. For the purpose of this program, a PTF is intended for an individual who (1) is a postdoctoral trainee, medical resident, or clinical fellow; or (2) has his or her own independent program of prion research; or (3) has his or her own established independent program of research with limited or no experience in the prion field.

The goal of the PTF is twofold: to encourage prion researchers to develop new expertise or receive training that would enable them to broaden the scope of their prion research and to attract investigators into the field of prion research by allowing them the opportunity to acquire the necessary skills/training. These awards may be taken at another institution, or within the same institution or department. The competitive applicant is expected to demonstrate clearly and convincingly that the proposed efforts will result in an enhancement of their pre-fellowship skills, particularly with respect to the development of antemortem diagnostics for the detection of transmissible spongiform encephalopathies (TSEs). Proposals should also include a discussion of the opportunities that the PTF will provide for critical professional interaction with senior colleagues. A letter of commitment from the collaborating investigator must be included as part of the proposal.

PTFs can be requested for up to $125,000 for up to 1 year, inclusive of direct and indirect costs. Direct costs can cover only salary and travel to scientific/technical meetings and/or the host laboratory. Funds for research must be provided from another resource.

For complete proposal requirements, please refer to Section VI-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VI-B and VI-C.

Submission of the same research project to the Fiscal Year 2002 National Prion Research Program (NPRP) under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different Principal Investigators (PIs). The Government reserves the right to reject any proposal.

VI-B. Scientific Peer Review Evaluation Criteria for Prion Techniques Fellowship Award Proposals

PTF proposals will be evaluated according to the following criteria:

- **Candidate:** Do the candidate's previous training, prior research experience, and publication record indicate promising achievements to date? Is there a need for the proposed research experience and training? Has the candidate demonstrated a personal commitment to pursuing a career in prion research?

- **Fellowship Experience:** Does the fellowship offer a valuable opportunity to acquire critical skills or learn new methods relevant to prion research? Does the applicant demonstrate that the scope of his or her research will be broadened as a result of this award? Is there evidence of an institutional commitment to relieve the candidate from other academic or clinical responsibilities in order to permit time for the fellowship? Is there evidence of a collaborator/mentor at the host institution with the appropriate TSE background, qualifications, research resources, and time to supervise the fellowship?

- **Scientific Relevance:** Does the application make a convincing case for the relevance of the fellowship to prion research? To what extent will the fellowship, if successful, assist the applicant with developing or enhancing a career in prion research?

- **Budget:** Is the budget appropriate?

VI-C. Programmatic Review Evaluation Criteria for Career Development Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the PTF mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VI-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are expected to submit a Letter of Intent no later than September 30, 2002 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/default

VI-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for PTF. Please note that the body of the proposal is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.**

Applicants must submit the Proposal Information at http://cdmrp.org/proposals prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdmrp.org/proposals by **11:59 p.m. (applicant's local time) October 30, 2002.** Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.
   An eligible applicant must: (1) be a postdoctoral trainee, medical resident, or clinical fellow; **or** (2) have his or her own independent program of prion research; **or** (3) have his or her own established independent program of research with limited or no experience in the prion field.

2. Proposal Acceptance Criteria – See Appendix B, part 2.
   Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

3. Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, PTF applicants should articulate (within the 1-page limit) how the combination of training value and relevance to any aspect of prion research will enable the applicant to acquire critical skills or learn new methods relevant to prion research, including the educational and/or training value of the proposed research relative to their career goals.

11. Proposal Body – See Appendix B, part 11.
    The body of PTF proposals is limited to **10 pages**.

    a. Career Development Plans: Briefly describe the candidate's career development plan and how the proposed experience and training will enhance or broaden the candidate's skills in the area of prion research. Discuss the applicant's research plans after the completion of this award.

    b. Description of Research Project: Applicants should provide an overview of how their time will be spent during their fellowship. A description of the methods that will be acquired during the fellowship and how those methods will be applied in the candidate's own research following the end of the fellowship should be provided.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.
    Funds for research support are a requirement of the PTF proposal. The PI should clearly indicate (1) the titles, time commitments, supporting agencies, duration, and levels of funding for all existing and pending research grants involving the PI and key personnel and (2) the level of support, source, and duration of any additional funds that would be applied to the PTF project (departmental funds, etc.).

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, provide a letter of commitment from the collaborating investigator in the Administration Documentation section of the proposal submission.

Note: Signed letter(s) of support from institutions and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
PTFs can be requested for up to $125,000 for up to 1 year, inclusive of direct and indirect costs. Direct costs can cover only salary and travel to scientific meetings. Funds for research must be provided from another source and should be noted in the Existing/Pending Support section. The amount allotted for travel is $1,800 per year to attend scientific/technical meetings.

    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, part 7 for more details.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet at http://cdmrp.org/proposals by **11:59 p.m. (applicant's local time) October 30, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues will be available through the CDMRP web site (http://cdrmp.army.mil). See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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Prion Techniques Fellowship Award Proposal
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