DEPARTMENT OF DEFENSE

FISCAL YEAR 2002
TUBEROUS SCLEROSIS COMPLEX RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT

March 8, 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) Tuberous Sclerosis Complex Research Program (TSCRP). The deadline, format, and other criteria specified for proposals in this DOD Fiscal Year 2002 (FY02) Program Announcement are based on program objectives, public needs, and regulatory guidance.

Specific information on the USAMRMC, U.S. Army Medical Research Acquisition Activity (USAMRAA), the Congressionally Directed Medical Research Programs (CDMRP), and the DOD TSCRP 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 (for information on completing the Proposal Information, see Section 5, page ii of this Foreword).

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 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 by an authorized Administrative Representative of the Sponsored Programs Office (or equivalent) of your organization by **11:59 p.m. (applicant's local time) on June 4, 2002**. See Appendix B, part 20, 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:	As soon as possible but no later than May 21, 2002
Proposal Receipt Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet by **11:59 p.m. (applicant's local time) on June 4, 2002.**
Peer Review:	July 2002
Request for RCQ[1] Documents:	As early as July 2002
Programmatic Review:	September 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	**Between November 2002 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 (TSCRP02-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.

Help lines will be available by May 7, 2002 to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (http://cdmrp.army.mil) and the proposal submission web site (http://cdmrp.org/proposals). Alternately, help can be obtained by e-mail at help-proposals-cdmrp@cdmrp.org.

5. Proposal Submission

Applicants should refer to Section III and Appendix B for appropriate submission requirements.

Proposals will be submitted electronically at http://cdmrp.org/proposals. The web site will be available for proposal submission by May 7, 2002. An authorized Administrative Representative from the Sponsored Programs Office of the applicant's organization must upload/submit one

[1] Regulatory Compliance and Quality

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. We encourage applicants 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, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.

3. Applicants will need to provide the Administrative Representative with an electronic copy of the proposal. 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 and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically to this program; 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) on June 4, 2002.** Detailed instructions for electronic submissions will be available by May 7, 2002 at http://cdmrp.org/proposals.

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, neurofibromatosis, tuberous sclerosis, Defense Women's Health, osteoporosis, 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. 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 for each award mechanism.

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. Consumer reviewers are individuals with tuberous sclerosis or their family members and representatives of consumer advocacy organizations. Consumer reviewers are nominated by an advocacy organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. 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). 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 will use to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic 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 a letter indicating the award status of his or her proposal, along with the peer review summary statement. Letters 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 discussions, 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 letter. All documents related to RCQ should be available on the CDMRP web site

(http://cdmrp.army.mil) by April 2002.

I-F. Human Use Requirements Unique to Department of Defense-Funded Research

Important distinctions exist for research funded by the DOD that involves human subjects. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects, a second, DOD review and approval is 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 specifically 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 Part 7, Appendix F 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 who 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 on the CDMRP web site (http://cdmrp.army.mil) by April 2002.

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 Tuberous Sclerosis Complex Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." A PI 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[1] 200 et seq.), 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] United States Code

II. Department of Defense Tuberous Sclerosis Complex Research Program

II-A. History of the Tuberous Sclerosis Complex Research Program

Tuberous sclerosis is a genetic disorder that can affect any or all systems of the body. Tuberous sclerosis affects as many as 25,000 to 40,000 individuals in the United States and about 1 to 2 million (M) individuals worldwide.[1] The Department of Defense (DOD) Tuberous Sclerosis Complex Research Program (TSCRP) is being established in fiscal year 2002 (FY02) to promote research directed toward a better understanding of the role and function of proteins produced by the TSC1 and TSC2 tumor suppressor genes, in accordance with the directives received from Congress. The DOD is using the model established through recommendations from the Institute of Medicine for the U.S. Army Medical Research and Materiel Command's (USAMRMC's) Breast Cancer Research Program (BCRP) to establish the TSCRP. Like the BCRP, the TSCRP will employ a two-tiered scientific review process consisting of scientific (peer) review and programmatic review. Congress appropriated $1M for the TSCRP in FY02.

II-B. Overview of the Fiscal Year 2002 Tuberous Sclerosis Complex Research Program

The Congressionally Directed Medical Research Programs (CDMRP) is requesting proposals on TSC research through this program announcement. Proposals will be requested for Idea Development Awards. Proposals are encouraged from investigators working at Historically Black Colleges and Universities/Minority Institutions.

II-C. Fiscal Year 2002 Tuberous Sclerosis Complex Research Program Announcement Award Opportunities

This command anticipates that approximately $850 thousand (K) will be available to fund competitive, peer reviewed TSC research.

Allocations	FY02
Congressional Appropriation	$1.0M
Less: Congressional/DOD Withholds[1]	$54.0K
Appropriation Received	$946K
Less: Approximate TSCRP Management Costs[2]	($95.0K)
Amount Available for FY02 Research	$851K

[1]Withholds include Small Business Innovation Research (SBIR)/USAMRMC.
[2]Any cost savings from management cost will be applied to research funding.

[1] National Institute of Neurological Disorders and Stroke Fact Sheet, 2001, and Harrison's *Principals of Internal Medicine*, 15th Edition, McGraw-Hill, 2001.

Prospective applicants who are familiar with the CDMRP program requirements from previous years are urged to review this program announcement carefully because revisions have been made.

III. Idea Development Awards

III-A. Idea Development Awards

Idea Development Awards are intended to encourage innovative research aimed at **understanding the role and function of proteins produced by the TSC1 and TSC2 tumor suppressor genes**. To be eligible for an Idea Development Award, an applicant must be an independent investigator at the level of Assistant Professor (or equivalent) or above. All Idea Development Award proposals must include preliminary data relevant to tuberous sclerosis research and the proposed project.

Funding for Idea Development Awards can be requested for a maximum of $425,000 for direct and indirect costs for a 2- to 3-year period. Direct costs can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

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

Idea Development Award proposals will be evaluated according to the following criteria:

- **Disease Relevance:** Does this study address the role and function of proteins produced by the TSC1 and TSC2 tumor suppressor genes? To what extent will the project, if successful, make an original and important contribution to advancing research in the tuberous sclerosis field? Does the proposal make a convincing case for the relevance of the research to tuberous sclerosis?

- **Research Strategy:** Are the conceptual framework, hypotheses, experimental design, methods, and analyses adequately developed and well integrated to the aims of the project? Is there a clear-cut rationale supporting the research provided? Does the applicant acknowledge potential problem areas and consider methods/alternative tactics? Do the required tuberous sclerosis-relevant preliminary data support the proposed project?

- **Innovation:** Is the proposed research innovative in one or more of the following areas: study concept or question; research methods or technologies; clinical interventions; adaptations of existing methods or technologies? Is it innovative in other ways? Are the aims original? Does the project propose new paradigms, or challenge existing paradigms? Is innovation necessary for the project?

- **Personnel:** Is the Principal Investigator (PI) appropriately trained and well suited to carry out this work? Does the PI show potential for contribution to the tuberous sclerosis field? Is the proposed work appropriate to the experience level of the PI and other researchers (if applicable)? Is appropriate expertise available to conduct the study successfully?

- **Environment:** Is the scientific environment appropriate for the proposed research? Do necessary resources and appropriate collaborative arrangements adequately support the research requirements? Is there evidence of institutional support provided with the proposal?

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

III-C. Programmatic Review Evaluation Criteria for Idea 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. 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 requested to submit an electronic Letter of Intent by May 21, 2002. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/default

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 Development 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 prior to peer review.** Applicants are required to submit the Proposal Information 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 by **11:59 p.m. (applicant's local time) on June 4, 2002.**

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 Idea Development Award applicants must be independent investigators at the Assistant Professor level (or equivalent) or above.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Proposal Information – See Appendix B, part 3 and Appendix C.

4. Title/Referral Page – See Appendix B, part 4.

5. Table of Contents – See Appendix B, part 5.
   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. 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 name (last name, first name, middle initial) and the proposal log number generated by the Proposal Information.

6. Checklist for Proposal Submission – See Appendix B, part 6.

7. Proposal Abstracts – See Appendix B, part 7 and Appendix D.

8. Statement of Work – See Appendix B, part 8 and Appendix D.

9. Proposal Relevance Statement – See Appendix B, part 9.
   In addition to the instructions found in Appendix B, part 9, Idea Development Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to tuberous sclerosis research. Describe how the combination of innovation and relevance in the proposal will contribute to advancing research in the tuberous sclerosis field.

10. Proposal Body – See Appendix B, part 10.
    The body of Idea Development Award proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used. The inclusion of promising and well-founded preliminary data relevant to tuberous sclerosis research and the proposed project is required for Idea Development proposals.

    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. Include preliminary data relevant to tuberous sclerosis research. Cite relevant literature references.

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

    c. Objectives: State concisely the project's specific aims and study design.

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

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

11. Abbreviations – See Appendix B, part 11.

12. References – See Appendix B, part 12.

13. Biographical Sketches – See Appendix B, part 13 and Appendix E.

14. Existing/Pending Support – See Appendix B, part 14.

15. Facilities/Equipment Description – See Appendix B, part 15.

16. Administrative Documentation – See Appendix B, part 16.
    Provide the following items in the Administrative Documentation section.

    Provide letter(s) of support from the institution and/or collaborating investigators in the Administrative Documentation section of the proposal submission.

    Note: The signed letter(s) of support from the institution 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 20).

17. Detailed Cost Estimate – See Appendix B, part 17 and Appendix F.
    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. Idea Development Awards can be requested for a maximum of $425,000 for direct and indirect costs for a 2- to 3-year period. Direct costs can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

    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 part 7 of Appendix F for more details.

18. Instruments – See Appendix B, part 18.

19. Publications and/or Patent Abstracts – See Appendix B, part 19.

20. Proposal Submission – See Appendix B, part 20.

21. Submission Deadline – See Appendix B, part 21.
    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 by **11:59 p.m. (applicant's local time) on June 4, 2002. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

22. Regulatory Compliance and Quality Requirements – See Appendix B, part 22.
    The 1-page Certificate of Environmental Compliance and 1-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. All documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 22 for more details.

Proposal Log Number: _____

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

Proposal Title: _____

Idea Development Award Proposal
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Lay Abstract (1-page limit) 4
Statement of Work (2-page limit) 5
Proposal Relevance Statement (1-page limit) ..... ___
Proposal Body (10-page limit) ..... ___
Abbreviations (1-page limit) ..... ___
References (no page limit) ..... ___
Biographical Sketches (3-page limit each)
PI (Idea Development Applicant) ..... ___
Key personnel (including collaborating investigators and support staff) ..... ___
Existing/Pending Support (no page limit) ..... ___
Facilities/Equipment Description (no page limit) ..... ___
Administrative Documentation (no page limit) ..... ___
List of items included in this section ..... ___
Letters of support from collaborating individuals or institutions ..... ___
Detailed Cost Estimate (no page limit) ..... ___
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