

Appendix A

Fiscal Year 2002 Chronic Myelogenous Leukemia Research Program Announcement Electronic 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 no later than September 4, 2002**. This form can be found on the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/02cmlrp1>

Appendix B

Proposal Preparation

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Proposal Preparation

1. Who May Apply

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. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution. The U.S. Army Medical Research and Materiel Command (USAMRMC) is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

Please refer to Section III for additional eligibility criteria.

Applicants are cautioned that awards are made to institutions. Should the applicant of a funded project leave the recipient institution, both the applicant and an official of the recipient institution should contact the U.S. Army Medical Research Acquisition Activity awarding office prior to the applicant leaving the recipient institution to discuss options available for continued support of the research project.

Historically Black Colleges and Universities/Minority Institutions

A goal of the Department of Defense (DOD) is to allocate funds for the Congressionally Directed Medical Research Programs' (CDMRP's) peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders¹ and is intended to "advance the development of human potential, provide quality education, increase opportunities to participate in and benefit from Federal Programs and strengthen the capacity of targeted institutions." An institution's minority status is established by the Department of Education (DOEd). Proposals submitted to the DOD are assigned HBCU/MI status if they are so designated by the DOEd on the date that the program announcement is released. The DOEd list is posted on the CDMRP web site at <http://cdmrp.army.mil/spp> under Minority Institutions. Any individual, regardless of ethnicity, nationality, or citizenship status, may apply for funding as long as they are employed by, or affiliated with, an eligible institution.

HBCU/MI proposals will be reviewed concurrently with all others in the same research area during scientific peer review, but may be evaluated separately during programmatic review when award recommendations are determined. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI submissions will be based upon scientific excellence and program relevance.

¹ Executive Orders 12876, 12900, and 13021

2. Proposal Acceptance Criteria

Please follow the compliance guidelines listed below when preparing your proposal. **Note that all proposals must be converted into an electronic PDF (Portable Document Format) file for electronic submission. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.**

Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner in order to assist scientific reviewers responsible for reviewing proposal merit. Scientific peer reviewers will expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements (such as font size, margins, line spacing, proposal components out of order) makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a poorer global priority score in scientific peer review. **Excess pages may result in administrative rejection prior to scientific peer review.**

For the preparation of proposals for PDF submission, it is required that the instructions in this section be followed carefully. The proposal must be clear and legible and conform to the following format, font size, spacing, margin, and printing guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Type Color: Black type for all graphs, diagrams, tables, and charts. The proposal should contain only material that can be photocopied. Investigators are cautioned that color graphs or photographs may not reproduce in subsequent photocopies. Therefore, submission of color figures, tables, graphs, or photographs is not recommended.
- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches. (Note to international applicants: The text of the proposal must not exceed 7.0 x 10.0 inches [approximately 19 cm x 25.5 cm].)

To assist applicants, the following example is included.

This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing.

Number all pages of the proposal consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the applicant's name (last name, first name, middle initial) and proposal log number (this will be automatically provided when a draft of the electronic Proposal Information is saved).

3. Proposal Information

Please complete the Proposal Information as described at <http://cdmrp.org/proposals>. See Section 5 pages ii and iii of the Foreword or [Part 20](#) of this Appendix (Proposal Submission) for more information regarding the complete electronic submission process.

4. Title/Referral Page - No page limit

Please complete the Title/Referral Page as described:

- a. Proposal title (up to 160 characters).
- b. Proposal log number (this will be automatically provided when a draft of the Proposal Information is completed and saved).
- c. Applicant's full name (first, middle initial, last).
- d. Award mechanism.
- e. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project (e.g., cell signaling, apoptosis, angiogenesis, drug delivery systems, gene therapy, x-ray crystallography, genetic counseling, quality of life, nuclear medicine, immunology, clinical oncology, nutrition).

- f. Conflicts of interest: Every effort is made to avoid real and apparent conflicts of interest during the peer review process. To assist the staff in this regard, list the names of all scientific participants in the proposal including the applicant, co-investigators, research associates, research assistants, consultants, collaborators, and subcontractors. In addition, list the names of other researchers outside the scope of this proposal that may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and role(s) on the proposed project or perceived conflicts of interest.

Title/Referral Page
No Page Limit

a. Proposal title (up to 160 characters)

--

b. Proposal log number

--

c. Applicant's full name (first, middle initial, last)

--

d. Award mechanism

--

e. Keyword descriptive technical terms

--

f. Conflicts of interest: Include the following information (no page limit)

Name	Institutional Affiliation(s)	Role(s) on Proposed Project or Perceived Conflicts of Interest

5. Table of Contents - Start section on a new page - 1-page limit

Prepare a Table of Contents, with page numbers, using the outline provided in Section III-E.

6. Checklist for Proposal Submission (Instructions)

The [Checklist](#) for FY02 Chronic Myelogenous Leukemia Research Program (CMLRP) Proposal Submission found on page B-8 must be completed and submitted with your PDF proposal. Place it immediately after the Table of Contents.

Complete and place this form immediately after the Table of Contents to confirm that all components are included in your application.

Checklist for FY02 CMLRP Proposal Submission

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Proposal Information completed
<input type="checkbox"/>	<input type="checkbox"/>	Title/Referral Page
<input type="checkbox"/>	<input type="checkbox"/>	Table of Contents
<input type="checkbox"/>	<input type="checkbox"/>	Checklist for FY02 CMLRP Proposal Submission
<input type="checkbox"/>	<input type="checkbox"/>	Technical Abstract (1-page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Lay Abstract (1-page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Statement of Work (2-page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Proposal Relevance Statement (1-page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Proposal Body (20-page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Abbreviations (1-page limit)
<input type="checkbox"/>	<input type="checkbox"/>	References (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Biographical Sketches (3-page limit per individual)
<input type="checkbox"/>	<input type="checkbox"/>	Principal Investigator
<input type="checkbox"/>	<input type="checkbox"/>	Collaborating investigators and other key personnel
<input type="checkbox"/>	<input type="checkbox"/>	Existing/Pending Support (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Facilities/Equipment Description (no page limit)
		<i>Administrative Documentation:</i>
<input type="checkbox"/>	<input type="checkbox"/>	List of items included in this section
<input type="checkbox"/>	<input type="checkbox"/>	Letters of support from collaborating individuals and/or institutions (if applicable)
<input type="checkbox"/>	<input type="checkbox"/>	Detailed Cost Estimate (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Total cost estimate matches Proposal Information
<input type="checkbox"/>	<input type="checkbox"/>	Instruments (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	List of documents included in Instruments Section
<input type="checkbox"/>	<input type="checkbox"/>	Publications and/or Patent Abstracts (5-document limit)
<input type="checkbox"/>	<input type="checkbox"/>	Certificate of Environmental Compliance
<input type="checkbox"/>	<input type="checkbox"/>	Principal Investigator Safety Program Assurance

NOTE: Exceeding page limits may result in proposal rejection prior to peer review. Submit only materials specifically requested or required in this program announcement. Submission of additional materials may be construed as an attempt to gain an unfair advantage.

7. Proposal Abstracts - Start each abstract on a new page - 1 page each

Both a 1-page structured technical abstract and a 1-page lay (nontechnical) abstract are required. Each proposal abstract page should contain the title of the proposal and the name of the applicant. Abstracts must be submitted as part of the proposal. **Do not include figures or tables in either abstract.**

These abstracts are vitally important to the review of the proposal. **Programmatic review is based upon the Integration Panel's review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submits abstracts that fully describe the proposed work.** Sample abstracts are included in [Appendix D](#) of this program announcement.

The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective or hypothesis and its supporting rationale, significance of the proposed work to the program's goals, specific aims of the study, and study design.

Please use the outline below for preparing the structured technical abstract.

- a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- b. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- c. Specific Aims: State concisely the specific aims of the study.
- d. Study Design: Briefly describe the study design.
- e. Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the program's goals. For example, how the study will prevent or improve the detection or treatment of the disease.

The lay abstract is intended to communicate the purpose of, and rationale for, the study to the non-scientific community. It should be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. The lay abstract should not duplicate the technical abstract.

Abstracts of all funded proposals will be posted on the CDMRP web site at <http://cdmrp.army.mil>. Thus, proprietary or confidential information should not be included in the abstract.

8. Statement of Work - Start section on a new page - 2-page limit

The Statement of Work (SOW) is a concise restatement of the research proposal that outlines and establishes the applicant's performance expectations and timeline for which the USAMRMC will provide financial support. Although some allowance is made for problems encountered and uncertainties that are part of research, the applicant is expected to meet the provisions and milestones in the SOW.

The SOW should be a series of relatively short statements that outline, step-by-step, how each of the major goals or objectives of the proposed research/services will be accomplished. As appropriate, the SOW should:

- a. Describe the work to be accomplished as tasks (tasks may relate to specific aims),
- b. Identify the timeline and milestones for the work over the period of the proposed effort,
- c. Indicate the numbers of research subjects (animal or human) for each task,
- d. Identify methods, and
- e. Identify products/deliverables for each phase of the project.

The SOW must not exceed 2 pages of single-spaced typing. Several sample SOWs are included in [Appendix D](#) of this program announcement.

9. Proposal Relevance Statement - Start section on a new page - 1-page limit

In the Proposal Relevance Statement, the investigator should describe how the proposed research/services are pertinent to one or more critical issues of the disease.

10. Proposal Body - Start section on a new page - 20-page limit

Investigators should refer to the specific evaluation criteria listed under "Proposal Body" in Section III-E (page III-4).

11. Abbreviations – Start section on a new page – 1-page limit

Provide a glossary of all acronyms, abbreviations, and symbols used.

12. References - Start section on a new page – No page limit

List all relevant references using a standard reference format that includes the full citation (i.e., author(s),

year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

13. Biographical Sketches - 3-page limit per investigator

Biographical sketches should be included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. Each biographical sketch must not exceed 3 pages. The Biographical Sketch form can be found in Appendix E or downloaded from the CDMRP web site at <http://cdmrp.army.mil/funding/02cmlrp1>

14. Existing/Pending Support - No page limit

List on a separate page, the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel. Proposals submitted under this program announcement should not duplicate other funded research projects. If no support exists, state “none.”

15. Facilities/Equipment Description - No page limit

Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for acquisition or available for use at no cost to the USAMRMC. Indicate if government-owned facilities or equipment are proposed for use.

16. Administrative Documentation - No page limit

The first item in this section must be a list of all the items in the Administrative Documentation section.

Provide letter(s) from the applicant’s institution and proposed collaborating individuals or institutions (if applicable) confirming support and collaborative efforts, respectively, that are necessary for the project’s success.

Note: This section is not for additional data, figures, or other similar information. Support documentation **will not** be accepted separately from the electronic proposal submission.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. All documents or letters requiring signatures must be signed and then scanned into the proposal prior to submission. Help lines are available to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone number is 301-466-6495. Help can also be obtained by e-mail at help-proposals@cdmrp.org.

17. Detailed Cost Estimate - No page limit

Budget is a key consideration in both scientific peer and programmatic review; applicants are cautioned to use discretion in budget requests. In addition, budgets will also be reviewed during award negotiations. Use the Detailed Cost Estimate Form to prepare a detailed cost estimate of the proposed research/services. This form can be found in [Appendix F](#) or downloaded from the CDMRP web site at <http://cdmrp.army.mil/funding/02cmlrp1> The cost of preparing proposals in response to this program announcement is not considered an allowable direct charge to any resultant award.

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 of [Appendix F](#) (Detailed Cost Estimate) for more details.

18. Instruments - No page limit

Include an appropriately titled page listing the documents you have in this section. Questionnaires, survey instruments, or clinical protocols that apply to the proposal should be included in this section.

19. Publications and/or Patent Abstracts - 5-document limit

Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, **the extra items will not be peer reviewed. Submit only material specifically requested or required in this program announcement. Submission of unrequested material may be construed as an attempt to gain a competitive advantage and will be removed.**

These documents must be incorporated into the electronic PDF version of your proposal. Help lines are available to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone number is 301-466-6495. Help can also be obtained by e-mail at help-proposals-cdmrp@cdmrp.org.

20. Proposal Submission

Electronic submission is required. No paper copy submissions will be accepted.

Proposals will be submitted electronically at <http://cdmrp.org/proposals>. One electronic PDF version of the proposal is required and will count as the official proposal submission. The electronic PDF proposal must be uploaded/submitted through the Internet by an authorized Administrative Representative from the Sponsored Programs Office (or equivalent) of your organization no later than **11:59 p.m. (applicant's local time) September 18, 2002** and must be accompanied by the Proposal Information, as described below.

Several steps are critical for successful electronic submission of your proposal.

1. The applicant is required to submit Proposal Information online 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. **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, 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. 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 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. Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the CDMRP web site no later than **11:59 p.m. (applicant's local time) September 18, 2002.** Detailed instructions for electronic submissions are available at <http://cdmrp.org/proposals>.

21. Submission Deadline

The submission deadline is 11:59 p.m. (applicant's local time) September 18, 2002. The electronic PDF version of your proposal must be sent through the Internet by the Sponsored Programs Office (or equivalent) of your organization by that time.

If your proposal is submitted electronically after 11:59 p.m. (applicant's local time) on September 18, 2002, it may not be considered for review.

22. Regulatory Compliance and Quality Requirements

The [Certificate of Environmental Compliance](#) (page B-15) and the [Principal Investigator Safety Program Assurance Form](#) (page B-16) are to be completed and included with the submitted proposal.

The Facility Safety Plan (if needed), Research Involving Animals, and Research Involving Human Subjects and/or Anatomical Substances documents should not be included with the submitted proposal; these documents will be requested in the applicant's notification letter and will be reviewed by Regulatory Compliance and Quality staff. These documents will be available on the CDMRP web site.

Specific Information Related to the Certificate of Environmental Compliance:

This form should be completed by the institution's official responsible for environmental compliance.

The Council on Environmental Quality (CEQ) regulations (40 CFR 1500-1508¹) that implement the National Environmental Policy Act (Public Law 91-190, as amended) require all federal agencies to examine possible environmental consequences of their proposed and ongoing actions.

The U.S. Army Medical Research and Materiel Command (USAMRMC) examines all medical research and development projects, whether inside or outside the United States, for their potential environmental impacts. In most cases, awardees conducting research in established laboratories that are in compliance with environmental laws and regulations, or are already covered by existing environmental documentation, will not be required to provide additional information about the environmental impact of their proposed research. Such projects will receive a "categorical exclusion" according to the Army regulations that implement the CEQ regulations (Army Regulation 200-2). If a proposal has been selected for award, the USAMRMC will determine if a categorical exclusion is warranted. If there are any extraordinary circumstances surrounding the research (e.g., research that involves the transfer of recombinant DNA molecules into the genome of one or more human subjects, requires Biosafety Levels 3 and 4, or uses animals captured from the wild), further information may be requested from the investigator to determine the environmental impact of the proposed research.

¹ Title 40, Code of Federal Regulations, Sections 1500-1508.

Certificate of Environmental Compliance

The offeror currently IS IS NOT (check appropriate category) in compliance with applicable national, state, and local environmental laws and regulations. (If not in compliance, attach details and evidence of approved mitigation measures.)

The offeror has examined the activities encompassed within the proposed action entitled

“

_____”

(enter title and Principal Investigator’s name), for compliance with environmental laws and regulations.

The offeror states that the conduct of the proposed action:

1. WILL NOT violate any applicable national, state, or local environmental law or regulation, and
2. WILL NOT have a significant impact on the environment.

The offeror agrees that if the work required under the proposed action at any time results in a significant impact on the environment or a violation of any applicable environmental law or regulation, the offeror will immediately take appropriate action, to include notifying and/or coordinating with the appropriate regulatory agencies as required by law and notifying the Grants Officer.

Name of Official Responsible for
Environmental Compliance

Signature

Title

Date

Name of Organization

Principal Investigator Safety Program Assurance

- ◆ I assure that I have involved the Facility Safety Director/Manager in the planning of this research proposal, discussed with him/her all aspects of the proposal that relate to occupational health and safety, and will help him/her prepare the annual Facility Safety Plan Status Report.
- ◆ I assure that I will comply with my institution's safety program and its requirements.
- ◆ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.
- ◆ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.
- ◆ I assure that hazards associated with my research have been identified, eliminated, and/or controlled.
- ◆ I assure that all Safety Plan requirements are in compliance with 32 CFR 626 and 627, "Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements" (*if applicable*).

Name of Principal Investigator (print)

Signature

Date

Mailing Address: _____

Street

City

State

Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____

Appendix C

Proposal Information

The Proposal Information and instructions for completing it are available at the Congressionally Directed Medical Research Programs-related web site <http://cdmrp.org/proposals>. One electronic PDF (Portable Document Format) version of the proposal is required and will count as the official proposal submission. Applicants should refer to Section III and [Appendix B](#) for appropriate submission requirements.

Several steps are critical for successful electronic submission of your proposal.

1. The applicant is required to submit Proposal Information online 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. **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, 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. 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 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. Proposal Information must be completed online and the PDF proposal uploaded/submitted through the web site (<http://cdmrp.org/proposals>) no later than **11:59 p.m. (applicant's local time) September 18, 2002**. Detailed instructions for electronic submissions are available 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.

Appendix D

Sample Abstracts and Statements of Work

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TECHNICAL ABSTRACT

Prediction of Chemotherapy Response by Magnetic Resonance Spectroscopy

Michael G. Garwood, Ph.D., Idea Award Recipient

Background: While adjuvant doxorubicin and cyclophosphamide (AC) chemotherapy clearly prolongs overall survival for women, the relative risk reduction is small. Since new agents, particularly the taxanes, have substantial activity in breast cancer, it is important to learn how to best employ these drugs and maximize benefit of adjuvant chemotherapy. A complete pathologic response (pCR) to neoadjuvant AC is associated with the best overall survival. Thus, discovering methods to predict a pCR to specific chemotherapy regimens in individual patients should have clinical importance.

Objective/Hypothesis: Because chemotherapy induces apoptosis in breast cancer cells, we hypothesize that magnetic resonance spectroscopy (MRS) can identify metabolites associated with apoptosis. MRS can detect these early changes rapidly and noninvasively.

Specific Aims: (1) Measure MRS changes in primary human breast cancers treated with AC neoadjuvant chemotherapy, and (2) determine how MRS changes correlate with tumor response detected by magnetic resonance imaging (MRI) and with complete pathology response at time of surgery. Our long-term goal is to develop MRS as a technique to individualize treatment decisions and maximize treatment benefit for women with breast cancer.

Study Design: Concentrations of cellular compounds in primary breast lesions will be measured noninvasively by proton (^1H) MRS. Patients will undergo MRI and MRS scanning prior to AC treatment and at 24 hours after the first treatment. Changes in the molecular concentrations measured by MRS after the first treatment will be correlated with pathologic complete response. Patients will also undergo an additional MRI scan after their fourth cycle of treatment for the purpose of judging whether anatomic depiction by MRI correlates with pCR determined at surgery.

Relevance: A major challenge in breast cancer treatment is to determine which chemotherapeutic agent will provide the most benefit for an individual patient. This project will establish whether in vivo MRS is a powerful tool to individualize treatment decisions and to maximize treatment benefit for women with breast cancer.

LAY ABSTRACT

Prediction of Chemotherapy Response by Magnetic Resonance Spectroscopy

Michael G. Garwood, Ph.D., Idea Award Recipient

Chemotherapy given after surgical treatment of breast cancer saves lives by killing residual breast cancer cells left after surgery. Chemotherapy given before or after surgery is equally effective. Chemotherapy given before surgery has one major advantage, the response to treatment can be measured. A minority of women treated in this way will have complete disappearance of the tumor at surgery. Perhaps not unexpectedly, these women have the lowest relapse rates and best survival. Therefore, response to chemotherapy prior to surgery can identify women who receive the most benefit from treatment. Since many drugs can effectively kill breast cancer cells, a major challenge in breast cancer treatment is to determine which chemotherapeutic agent will provide the most benefit for an individual patient. The purpose of this proposal is to use magnetic resonance spectroscopy (MRS) to measure chemotherapy induced cell death. MRS can directly measure metabolites in tumors, and we hope to show that changes in metabolite levels measured immediately after chemotherapy treatment will identify tumors that will completely disappear with chemotherapy treatment. By performing these studies, we hope to develop a new technique that will be used to individualize and maximize the benefits of chemotherapy for breast cancer patients.

TECHNICAL ABSTRACT

Characterization of the Role of Hepatocyte Growth Factor in Genetically Defined Human Breast Cancer Cell Metastasis

Sendurai A. Mani, Ph.D., Postdoctoral Fellowship Award Recipient

Background: Hepatocyte growth factor (HGF), also known as scatter factor, is a multifunctional cytokine mainly produced by cells of mesenchymal origin. It elicits a variety of cellular responses in a paracrine fashion on neighboring epithelial cells expressing the Met tyrosine kinase receptor. HGF-Met signaling is essential during mouse development since inactivation of either the ligand or the receptor in mice leads to embryonic lethality. HGF-Met signaling has also been shown to be essential for wound healing, tissue regeneration, and the mammary gland development. The Met receptor was first identified as a constitutively active *tpv-met* oncoprotein in a human osteogenic sarcoma cell line that has the ability to transform NIH3T3 cells. Additionally, Met and HGF have also been found to be overexpressed or amplified in a variety of metastatic tumors, including human breast cancers. Also, the creation of an autocrine loop by co-expressing the unaltered form of Met and HGF in NIH3T3 cells has been shown to be oncogenic. Finally, overexpression of HGF in the non-metastatic cell line MDA MB 435 and other cancer cell lines enhanced the metastatic potential of these cells.

Objective/Hypothesis: I propose to study the role of HGF-Met signaling in inducing metastasis in genetically defined non-metastatic and angiogenic human breast cancer cells (HMLER), developed in our laboratory. These cells are transformed by introducing SV40 Large T antigen, the Val 12 *H-ras* oncogene, and the catalytic subunit of the human telomerase enzyme to the primary human mammary epithelial cells. Studies on HGF-mediated metastasis were performed in cell lines derived from tumor patients having several unknown genetic mutations; therefore, it is very difficult to predict the exact role played by HGF in inducing metastases in those genetically ill defined cells. HGF might have cooperated with other genes in order to induce metastases. HMLER cells will serve as a good model system to understand the role of HGF in inducing metastasis since we know the exact genetic changes introduced into these cells.

Specific Aims: (1) Determine the role of HGF in motility and invasion in genetically defined human breast cancer cells in vitro, and (2) determine the role of HGF in metastasis in genetically defined human breast cancer cells in vivo.

Study Design: HMLER cells express the met receptor but not HGF. I will therefore test whether the HMLER cells can respond to externally added HGF regarding cell scattering, cell motility, and tubule formation. I then will create an autocrine loop in HMLER cells by stably expressing the HGF gene using a retrovirus and analyze these cells for their ability to respond to the autocrine loop using the above assays. I will further characterize the HMLER-HGF cells for metastasis. If I find metastases, then I will try to understand the role of downstream signaling pathway in inducing metastases. If I do not find metastatic behavior in HMLER-HGF cells, then I will look for cooperating genes to induce metastases. For this, I will introduce a retroviral library made from MDA-MB 435 cells into HMLER-HGF cells and assay for metastasis.

Relevance: The HGF and c-Met are overexpressed and/or amplified in a variety of metastatic tumors. HGF and c-Met have been implicated in human tumor development and metastasis. Blocking HGF signaling was shown to inhibit invasion in a variety of tumors cell lines. Similar results were obtained upon downregulating Met expression. HGF-Met signaling thus serves as a promising target for therapeutic intervention in malignant diseases.

LAY ABSTRACT

Characterization of the Role of Hepatocyte Growth Factor in Genetically Defined Human Breast Cancer Cell Metastasis

Sendurai A. Mani, Ph.D., Postdoctoral Fellowship Award Recipient

Spreading of cancer cells from the primary tumor to other parts of the body is known as metastasis and is often the ultimate life-threatening stage of this disease. However, very little is known about the underlying genetic and cellular mechanisms of metastasis, and it is essential that we understand these mechanisms to develop a therapeutic intervention strategy. Most of the organs in the human body are made up of two types of cells, epithelial cells and mesenchymal cells, whereby more than 90% of human tumors arise from epithelial cells. Both epithelial cells and mesenchymal cells communicate with each other through small messenger molecules. Growth of these cells is normally kept under tight control. Also, epithelial cells are connected with one another, so they cannot move freely.

A small messenger molecule normally secreted by mesenchymal cells, called hepatocyte growth factor (HGF), has been shown to be present at abnormally high levels in the serum of metastatic breast cancer patients. This factor is also found elevated in other types of metastatic cancers. Under normal conditions, this factor is involved in breast development in the adult and also in embryonic organ development.

During cancer progression, this small messenger helps tumor cells to detach from their neighbor, stimulate the production of proteases, and induce tumor cell movement. During later stages of cancer development, the epithelial tumor cell starts producing this factor instead of depending on the mesenchymal cells.

To study the role of HGF in cancer metastasis, scientists normally use epithelial tumor cells derived from patients, which would have had much unknown damage in the genome. But recently, in our laboratory, Dr. William Hahn has converted a normal cell to a tumor cell by altering the function of few known genes. Most importantly, these cells form tumor in mice but they are not metastatic. These genetically defined cancer cells as opposed to genetically undefined cancer patient's tumor cells will serve as a good experimental model system to study metastasis. Since HGF is thought to induce metastasis in the tumor cells, I would like to develop a model system to study the role of HGF in inducing metastases by introducing the HGF gene into the non-metastatic human cancer cells. Development of this defined model system could be useful for the development of strategies specifically to block tumor cell invasion and metastasis.

Statement of Work

Development of Peptide Inhibitors of the “Cancer” Receptor (CR)

- Task 1.* To identify the minimal region of the CR polypeptide able to inhibit intact CR when co-expressed in cultured cells (Months 1-18):
- a. Develop a series of plasmids for expressing the CR open reading frame (Months 1-7).
 - b. Perform assays to ascertain which fragments of CR block DNA-binding (Months 7-18).
 - c. Confirm that fragments of the CR open reading frame that block DNA-binding activity also inhibit CR function *in vivo* (Months 18-24).
- Task 2.* To identify short peptides modeled after the receptor that act as inhibitors of DNA binding and subunit association (Months 18-36):
- a. Obtain synthetic CR peptides (Months 18-21).
 - b. Test the effect of synthetic peptides on the DNA-binding activity of CR (Months 20-24).
 - c. Characterize the inhibitory potency of active peptides and attempt to optimize the effect by testing additional overlapping peptides (Months 21-36).
 - d. Perform feasibility experiments to assess the ability of selected peptides to inhibit CR function in cultured cells (Months 20-36).

Statement of Work

Ultrasound Imaging

Task 1. Modification of ultrasound imaging gantry, Months 1-12:

- a. Modify imaging gantry to permit measurements of the optics.
- b. Perform measurements using a multi-modal scanning configuration.
- c. Design of final optics.

Task 2. Extensive evaluation of ultrasound imaging gantry with the final optics, Months 13-36:

- a. Repeat measurements using the final optics.
- b. Measure the contrast improvement provided by the new detector configuration relative to conventional detector configuration.
- c. Conduct specimen experiments to evaluate the increase in resolution provided by the magnification.
- d. Investigate the extent of artifacts in fixed and scanning modes.
- e. Participate in design of a clinical evaluation study comparing modified ultrasound mammography with conventional mammography.

Statement of Work

Follow-up Care for Men and Women with Cancer

Task 1. Develop Plan for Follow-up Patient Interviews, Months 1-3:

- a. The tracking system shell from the previous cancer project will be modified to track patient recruitment and contact process.
- b. The follow-up patient interview will be pre-screened with cancer patients from our hospital who are not enrolled in our study and modifications will be incorporated.
- c. The environmental process interview (EPI) used for the baseline interview will be adapted for the follow-up interview.
- d. Institutional Review Board approval will be obtained from all hospital sites.
- e. The patient interviewer will be trained in medical terminology, measures of the interview, and use of the modified EPI system.

Task 2. Preparation for Medical Record Abstractions, Months 3-9:

- a. The Medical Record Abstract form will be finalized and the investigator trained to perform patient data reviews using the instrument.
- b. The Medical Record Abstract form will be revised for direct computer data entry.

Task 3. Subject Recruitment and Data Collection, Months 9-20:

- a. Patients enrolled in our previous study will be recruited for the proposed follow-up study.
- b. Interviews subsequent to the first follow-up will be modified as necessary to reflect issues relevant to patients beyond the period of adjuvant therapy.
- c. Surveys will be sent to and data collected from enrolled patients every 6 months.

Task 4. Abstraction of Medical Records, Months 12-24:

- a. Medical record abstractions will be performed for surviving enrolled patients annually.
- b. Data entry and quality control measures will be ongoing.
- c. Follow-up interviews will be conducted once annually with surviving enrolled patients over the 4-year study period.

Task 5. Interim Analyses, Months 24-44:

- a. Interim statistical analyses of data obtained from interviews and medical record abstractions will be performed periodically.
- b. Annual reports will be written.

Task 6. Final Analyses and Report Writing, Months 44-48:

- a. Final analyses of data from interviews and medical record abstractions will be performed.
- b. A final report and initial manuscripts will be prepared.

Appendix E

Biographical Sketches

Provide the following information for the key personnel listed on page 1 of the Detailed Cost Estimate Forms (see Appendix F) for the initial budget period.			
NAME		POSITION TITLE	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
<p>RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past 3 years and representative earlier publications pertinent to this application. PAGE LIMITATIONS APPLY. DO NOT EXCEED THREE PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.</p>			

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED THREE PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED THREE PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.

Appendix F

Detailed Cost Estimate Form Instructions

The following sections describe the categories of costs that should be recorded on the Detailed Cost Estimate Form. All amounts entered should be in U.S. dollars.

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11. Total Costs for the Entire Proposed Period of Support	F-4
12. Justification	F-5
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Detailed Cost Estimate Form.....	F-6

1. Personnel

- **Name:** Starting with the applicant, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the applicant of the proposal.
- **Role on Project:** Identify the role of each individual listed on the project. Describe his or her specific functions in the Justification section of the [Detailed Cost Estimate form](#).
- **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the offering organization. The Department of Defense (DOD) staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent, note this with an asterisk (*) and provide a full explanation in the "Justification" section of the Detailed Cost Estimate Form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual institutional base salary for each individual listed for the project.
- **Percentage of Effort on Project:** The qualifications of the applicant and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.
- **Salary Requested:** Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.
- **Fringe Benefits:** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors. A copy of the rate agreement or other documentation to support the fringe benefits should be provided.
- **Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.

2. Consultant Costs

Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants, other than those involved in consortium arrangements.

3. Major Equipment

It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

4. Materials, Supplies, and Consumables

A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, and radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used.

5. Travel Costs

The amount allotted for travel costs for the Investigator-Initiated Research Award is \$1,800. Please enter the amount specified for travel in the [Detailed Cost Estimate Form](#).

6. Research-Related Subject Costs

Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The U.S. Army Medical Research and Materiel Command (USAMRMC) will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

7. Research-Related Injury Medical Costs

Indicate costs for medical care for research-related injuries, should an injury to the subject occur as a result of the subject's participation in the proposed research. If the institution or state provides for this medical care as part of their existing liability insurance, annotate a cost of \$0.00 and indicate in the Justification section of the Detailed Cost Estimate Form that medical care for research-related injuries will be covered by existing institution/state insurance. If additional funds are needed to either supplement an existing policy or purchase a separate insurance policy to meet this requirement, annotate the budget requested and indicate in the Justification section of the Detailed Cost Estimate Form how medical care for research-related injuries will be covered, and whether the cost is charged as direct or indirect costs. The institution business office can assist applicants with budgeting for this requirement. Subject costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

8. Other Expenses

Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (giving hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

9. Consortium Costs

A description of services or materials that are to be awarded by subcontract or subgrant is required. For awards totaling \$10,000 or more, provide the following specific information:

- a. the identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- b. the identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- c. whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- d. the proposed acquisition price.

10. Indirect Costs (overhead, general and administrative, and other)

The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. A copy of the negotiation memorandum should be provided.

11. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form)

Enter the totals under each budget category for all additional years of support requested and itemize these totals in the Justification section of the Detailed Cost Estimate Form. **Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. Also, explain any escalations of the budget from the initial to the future year(s) of support.** All amounts should be in U.S. dollars. Total costs for the entire proposed period of support on the last line of the second page should agree with the amount entered in the Proposal Information (see [Appendix C](#)).

12. Justification (third page of the Detailed Cost Estimate Form)

Each item in the budget should be clearly justified under the [Justification section](#) of the Detailed Cost Estimate Form. If applicable for research using human subjects, include how medical care for research-related injuries will be covered.

13. Relocation of Applicant

Awards are made to institutions. If the applicant leaves the recipient institution, both the applicant and an official of the recipient institution should notify the U.S. Army Medical Research Acquisition Activity before the applicant leaves to discuss options for continued support of the research project.

Detailed Cost Estimate Form

Name of Applicant (*last, first, middle*)

DETAILED BUDGET					FROM	THROUGH	
PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	% EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	Applicant						
SUBTOTALS ® ® ® ® ®							\$
CONSULTANT COSTS							
MAJOR EQUIPMENT (ITEMIZE)							
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)							
TRAVEL COSTS							
RESEARCH-RELATED SUBJECT COSTS							
RESEARCH-RELATED INJURY MEDICAL COSTS							
OTHER EXPENSES (ITEMIZE BY CATEGORY)							
SUBTOTAL OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD →→→→→							\$
CONSORTIUM COSTS	DIRECT COST						
	INDIRECT COST						
TOTAL PERSONNEL AND OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD							\$
TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD							\$
TOTAL COSTS FOR INITIAL BUDGET PERIOD							\$

Name of Applicant (*last, first, middle*)

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT						
BUDGET CATEGORY TOTALS*	INITIAL BUDGET PERIOD <small>(FROM FORM PAGE 1)</small>	ADDITIONAL YEARS OF SUPPORT REQUESTED				TOTAL
		2nd	3rd	4th	5th	
PERSONNEL						
FRINGE BENEFITS						
CONSULTANT COSTS						
MAJOR EQUIPMENT						
MATERIALS, SUPPLIES, AND CONSUMABLES						
TRAVEL COSTS						
RESEARCH-RELATED SUBJECT COSTS						
RESEARCH-RELATED INJURY MEDICAL COSTS						
OTHER EXPENSES						
SUBTOTAL DIRECT COSTS						
CONSORTIUM COSTS	DIRECT					
	INDIRECT					
TOTAL DIRECT COSTS						
TOTAL INDIRECT COSTS						
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT THIS AMOUNT SHOULD AGREE WITH THAT ENTERED IN THE PROPOSAL INFORMATION					\$	

* Itemize all budget categories for additional years on the Justification page that follows.

Appendix F

JUSTIFICATION: FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

Appendix G

General Information

Appendix G of this program announcement contains general information relating to U.S. Army Medical Research and Materiel Command (USAMRMC) policies and procedures.

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General Information

1. U.S. Army Medical Research and Materiel Command Award

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. Proposals selected for funding are processed by the U.S. Army Medical Research Acquisition Activity (USAMRAA).

All awards are made to organizations, not individuals. An applicant should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support.

2. Disclosure of Information outside the Government

By submission of an application, the applicant understands that disclosure of information outside the Government shall be for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that information in the proposal will only be used for evaluation purposes and will not be further disclosed or utilized. Funded projects may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding will not be subject to public release.

3. Award Eligibility

To be eligible for award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (Office of Management and Budget Circular A-110).

4. Government Obligation

Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants or organizations that make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

5. Information Service

Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. To the extent practical, all other sources should also be consulted for the same purpose.

6. Funding Instrument

All awards under this program announcement are anticipated to be grants or cooperative agreements.

More information on these funding instruments may be obtained by request from:

Fax: 301-619-2937
E-mail: q&a.baa@det.amedd.army.mil
Mail: Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA
820 Chandler Street
Fort Detrick, MD 21702-5014

7. Inquiry Review Panel

Applicants can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the Congressionally Directed Medical Research Programs staff, USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

8. Equipment/Property

It is the policy of the Department of Defense that all commercial and non-profit recipients possess the equipment and facilities needed to support proposed research. In those rare cases when additional specific equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.

Title to equipment or other tangible property purchased with grant or cooperative agreement funds may be vested in non-profit institutions of higher education or with non-profit organizations whose primary purpose is the conduct of scientific research. Normally, title will vest with the recipient organization if vesting will facilitate scientific research performed by the institution or organization for the Government.

Appendix H

Acronym List

BCRP	Breast Cancer Research Program
CDMRP	Congressionally Directed Medical Research Programs
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CML	Chronic Myelogenous Leukemia
CMLRP	Chronic Myelogenous Leukemia Research Program
DOD	Department of Defense
DOEd	Department of Education
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IIRA	Investigator-Initiated Research Award
IP	Integration Panel
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code