Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

A. Title of Award: Therapeutic Development Award (TDA).

B. Program Name: Department of Defense Fiscal Year 2004 Chronic Myelogenous Leukemia Research Program (CMLRP).

C. Funding Opportunity Number: CML04-TDA.

D. Agency Name: US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

E. Agency Contact(s):

1. Questions related to the Program, proposal format, or required documentation: Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-PLF (CML04-TDA)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website: https://cdmrp.org/proposals (the proposal submission website)
E-mail: help-proposals-cdmrp@cdmrp.org

F. Anticipated Instrument Type(s): Grants/Cooperative Agreements.

G. Catalog of Federal Domestic Assistance (CFDA) Number(s): 12.420; Military Medical Research and Development.

H. Website to Access Application Package: Proposals must be submitted electronically at https://cdmrp.org/proposals. This website will contain all the information, forms, documents, and links you will need to apply.

I. Award/Regulatory Approval: Please note, each award mechanism has specific requirements regarding human subjects and animal use. Please see the full text of the Program Announcement for details pertaining to this award mechanism. Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or use of laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Therapeutic Development Award mechanism is to sponsor the preclinical assessment of therapeutics, as well as the development of tools for the preclinical evaluation in model systems for CML.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately $3.7 million (M) is available for this award mechanism.
- Although there are no total dollar amount restrictions to these awards, programmatic priority will be given to smaller-scale, cost-efficient projects with well-defined endpoints. Funding can be requested for up to 3 years. Depending on the number and quality of the applications, it is anticipated that approximately three to four proposals will be funded. The CMLRP Integration Panel reserves the right to partially fund any proposal.

IV. ELIGIBILITY INFORMATION

A. Applicants: All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations.

C. Cost Sharing: It is expected that institutions will cost share. Please see "Major Equipment" located in Subsection V.F.2.c of the Full Text of Program Announcement for details.

D. Other Eligibility Criteria: Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Information: Applicants are required to submit the Proposal Information prior to upload of the proposal. Complete the Proposal Information as described at https://cdmrp.org/proposals.

B. Proposal Preparation: All proposals must be converted into an electronic PDF (Portable Document Format) file for electronic proposal submission. Please see the Full Text of Program Announcement for details.

C. Submission Dates and Times: Deadline Date: July 27, 2004. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

D. Electronic Submission Requirements: Electronic submission is required. No paper copy submissions will be accepted. Proposals must be submitted electronically at https://cdmrp.org/proposals. Please see the Full Text of Program Announcement for details.

VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tiered review process for proposals: scientific peer review, followed by programmatic review. Details of both tiers of review can be found in the Full Text of Program Announcement.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures, and administrative requirements including Regulatory Compliance and Quality documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of Program Announcement.

B. Reporting Requirements: Annual reporting requirements apply.

Full Text of Program Announcement

I. GENERAL INFORMATION

A. Title of Award: Therapeutic Development Award (TDA).

B. Program Name: Department of Defense (DOD) Fiscal Year 2004 (FY04) Chronic Myelogenous Leukemia Research Program (CMLRP).

C. Funding Opportunity Number: CML04-TDA.

D. Agency Name: US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

E. Agency Contact(s):

1. Questions related to the Program, proposal format, or required documentation: Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-PLF (CML04-TDA) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: Help lines will be 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 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website:	https://cdmrp.org/proposals (the proposal submission website)
E-mail:	help-proposals-cdmrp@cdmrp.org

F. Anticipated Instrument Type(s): The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

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

G. Catalog of Federal Domestic Assistance (CFDA) Number 12.420: Military Medical Research and Development.

H. Website to Access Application Package: Proposals must be submitted electronically at https://cdmrp.org/proposals. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

I. Award/Regulatory Approval: Please note, each award mechanism has specific requirements regarding human subjects and animal use. Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or use of laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Therapeutic Development Award is part of the DOD CMLRP, which was established in FY02 to promote innovative research directed toward eliminating chronic myelogenous leukemia (CML). Appropriations for the CMLRP since FY02 total $9.25 million (M). Due to the abundance of scientifically meritorious proposals received in FY02, a portion of the FY03 appropriation was used to fund four additional proposals received in FY02. All remaining FY03 funds were set aside to fund Hypothesis Development Awards, which are currently under review. The program history of the FY02-03 CMLRP is shown in Table 1. The FY04 appropriation is $4.25M.

Table 1: History of the DOD's Peer Reviewed CMLRP

Program History	FY02	FY03
Congressional Appropriations for CMLRP	$5M	$4.25M
Total Investigator Initiated Research Proposals Received	48	N/A[1]
Total Investigator Initiated Research Awards Funded	6	4

[1] Not applicable. Due to the abundance of scientifically meritorious proposals received in FY02, a portion of the FY03 appropriation was used to fund proposals received in FY02.

B. Program Objectives: The objectives of the FY04 CMLRP are to improve (1) the understanding of the basic science of CML, (2) the diagnosis of CML, (3) the treatment of CML, and (4) the quality of life for individuals and their families living with CML.

The intent of the Therapeutic Development Award mechanism is to sponsor the preclinical assessment of therapeutics, as well as the development of tools for the preclinical evaluation in model systems for CML. The overall goal of this award mechanism is to allow CML investigators to develop the means to analyze preclinical efficacy of novel and existing agents and/or to generate the preclinical data necessary to conduct clinical trials after completion of the proposed research. The Therapeutic Development Award is restricted to research in CML. The proposed studies are expected to be empirical in nature and product driven, but may have a hypothesis-driven approach provided the focus is on therapeutics. It is anticipated that the agents, model systems, or data generated from these awards will lead to the advancement of therapeutics novel to CML and to the development of a broad platform on which to test future therapies. The ultimate goal is to significantly move closer to the development of new therapeutics for CML.

Specific programmatic interests include proposals that:

- Develop and/or validate high-throughput screens or models to aid in defining novel targets with therapeutic potential, with a special emphasis on novel secondary pathways in CML;
- Screen libraries of small molecule compounds for identification of novel therapeutics or lead agents for CML;
- Develop novel or modify existing preclinical model systems and/or validate these model systems for elucidating the mechanisms of action of lead compounds and potential therapeutics for CML;
- Evaluate existing pharmacologic and/or novel agents to determine their effect(s) on the molecular mechanisms involved in CML;
- Adapt and/or validate preclinical model systems to make them suitable for CML pharmacological and/or pharmokinetic testing;
- Test new therapeutic modalities, including agents, delivery systems, and/or chemical modification of lead compounds, for CML using established or validated novel preclinical model systems;
- Design and implement full-scale, pilot Good Manufacturing Practice (GMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials;
- Develop pharmacologic agents through Adsorption, Distribution, Metabolism, Excretion and Toxicity (ADMET) phase; and/or
- Develop pharmacologic agents to Investigational New Drug (IND) stage for the initiation of Phase 1 clinical trials, including the compilation of data necessary for IND application.

Biotechnology and pharmaceutical companies are encouraged to apply for this award mechanism. If a biotechnology or pharmaceutical company applies for this mechanism as an individual submitter or as a part of a consortium (see below), the company is expected to leverage its own resources to complement the funding provided for the study by this award.

The preclinical drug development process may require resources beyond those available at a single institution. Therefore, **Therapeutic Development Awards are open to investigators interested in establishing synergistic, goal-focused, multi-institutional consortia (e.g., between industry and academia or among multiple academic institutions) focused on developing and validating animal models for their use in preclinical testing, identifying lead agents, and testing the clinical potential of the lead agents developed by the investigators.** The formation of consortia between biochemists and molecular biologists focused on target validation and evaluation is encouraged. If a consortium is proposed, sufficient characterization of the consortium and justification for the collaborative partners must be included in the proposal. Letters confirming/supporting collaboration are required. In addition, participating institutions must be willing to resolve potential intellectual property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful establishment and maintenance of the research

projects and the consortium as a whole. An intellectual property plan agreed upon by all institutions within the consortium is required as part of the administrative documentation of this proposal (see Subection V.E.13).

All applicants for Therapeutic Development Awards *must include preliminary data* relevant to the phase(s) of the preclinical drug development process covered by the research in their proposals. If appropriate, the proposal should include a clear statistical plan of analysis.

III. AWARD INFORMATION

Although there are no total dollar amount restrictions to these awards, programmatic priority will be given to smaller-scale, cost-efficient projects with well-defined endpoints. Funding can be requested for up to 3 years. Direct costs can cover salary, expenses including research supplies, and travel to scientific meetings. The amount for travel may not exceed $1,800 per year per investigator. Institutional support and commitment must be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. If a biotechnology or pharmaceutical company applies for this mechanism as an individual submitter or as a part of a consortium, the company is expected to leverage its own resources to complement the funding provided for the study by this award. For proposals involving a consortium, direct costs can also cover expenses for meetings that bring together members of the consortium.

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. Approximately $3.7M is available for this award mechanism. Depending on the number and quality of the applications, it is anticipated that approximately three to four proposals will be funded.

IV. ELIGIBILITY INFORMATION

A. Applicants: All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined below.

B. Institutions: 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. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

C. Cost Sharing: It is expected that institutions will cost share when appropriate. Please see full details under "Major Equipment" located in Subsection V.F.2.c.

D. Other Eligibility Criteria:

1. Duplicate Submissions: Submission of the same research project to other CDMRP programs is discouraged. However, if similar research projects are submitted to other FY04 program announcements within the CDMRP, the applicant must provide a strong justification for submitting duplicate proposals and the proposal's relevance to CML in the "Proposal Relevance Statement." The Government reserves the right to reject duplicative proposals.

2. HBCU/MI: A goal of the DOD is to allocate funds for the CDMRP's peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.[1] Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website under Minority Institutions at http://cdmrp.army.mil/funding/pdf/micmlrp020904.pdf.

3. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements 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 lower global priority score.

The following will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.
- Required administrative documentation is not included.

For any other sections of a proposal with a defined page limit, any pages over the specified limit will be removed from the proposal and not forwarded for peer review.

Unless specifically requested by the CDMRP, any material submitted after the submission deadline will not be forwarded for peer review.

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The Principal Investigator (PI) is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.
- **Statement of Work (SOW) and Proposal Abstracts:** The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the "Required Files" tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the "Required Files" tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance Form are each uploaded as separate PDF files under the "Required Files" tab.

[1] Executive Orders 12876, 12900, and 13021

The Contract Representative or institutional official responsible for sponsored program administration (or equivalent) from the applicant's institution is responsible for the following:

- **US Army Medical Research Acquisition Activity (USAMRAA) Documents:** The institute's currently negotiated "Rate Agreement," "Certifications and Assurances for Assistance Agreements," and the "Representations for Assistance Agreements" are to be uploaded as separate PDF files under the Contract Representative's "My Profile" tab.
- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration must provide approval of all proposal components (Proposal Information, SOW, Abstracts, Proposal, Budget Information, and Regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) July 27, 2004. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as described in https://cdmrp.org/proposals. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than 4 weeks prior to the July 27, 2004 deadline. To accomplish this, the applicant should complete Part 1 of the Proposal Information section at https://cdmrp.org/proposals, then save the information by clicking on the "Save and Forward Letter of Intent" button. This information may be changed at any time until the applicant submits the final Proposal Information by clicking on the "Submit Final" button.

C. SOW – 11,400-character limit, including spaces (approximately two pages): The SOW is captured as a data field under the "SOW/Abstract" tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW, or "cut and paste" it from a word processing application into the data field. Sample SOWs can be found at https://cdmrp.org/samples.cfm.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services will be accomplished during the timeline for which the USAMRMC will provide financial support.

As appropriate, the SOW should:

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

D. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important to both the peer and programmatic review process.

Programmatic review is based upon the Integration Panel's (IP's) review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work.

Each abstract must contain the title of the proposal and the name of the PI. Each abstract must be submitted as a data field under the "SOW/Abstracts" tab of the CDMRP eReceipt system. Applicants can either type in their abstracts, or "cut and paste" them from a word processing application into the respective data fields. Do not include figures or tables in either abstract. Spell out all Greek or other non-English letters.

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

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. 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, specific aims of the study, study design, and significance of the proposed work to the program's goals.

Use the outline below for preparing the structured technical abstract.

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

2. Public Abstract: Sample public abstracts can be found at https://cdmrp.org/samples.cfm. The public abstract is intended to communicate the purpose of, and rationale for, the study to non-scientific audiences. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. It must be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. **The public abstract should not be a duplicate of the technical abstract**, but should describe the goals and objectives of the research project, and its relevance to the program.

In addition to describing the project, the public abstract must answer the following questions:

(1) What will the ultimate applicability of the research be?
- What types of patients will it help and how?
- What are the potential clinical applications, benefits, and risks?
- What is the projected time it may take to achieve a consumer-related outcome?

(2) If the research is too basic for clinical applicability, what are the interim outcomes?

- What types of contributions will this study make to advance research?
- How will the research enhance this or other studies being conducted?

E. Proposal:

1. Format: All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following 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.
- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- 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 (approximately 18 cm x 25.5 cm).

2. Title/Referral Page: No page limit. Complete the Title/Referral Page, which can be downloaded from the CDMRP website at https://cdmrp.org/programAnnouncements.cfm. Complete each section as described:

a. Proposal title (up to 160 characters).

b. Proposal log number (this will be automatically provided when the Proposal Information is completed and saved).

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

d. Submitting Institution.

e. Award mechanism: Type in "Therapeutic Development Award."

f. Indicate if this is a NEW proposal or a DUPLICATE proposal to other FY04 CDMRP program announcements.

g. 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.

h. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, his or her role(s) on the proposed project.

3. Table of Contents/Checklist: Start section on a new page; one-page limit. Prepare a Table of Contents/Checklist, with page numbers. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page.

4. Proposal Relevance Statement: Start section on a new page; one-page limit. Applicants should state explicitly how the proposed work is relevant to CML, and describe how the proposed research/services are pertinent to one or more critical issues of the disease. Describe how the combination of innovation and relevance of the proposal will contribute to the goals of conquering CML and advancing research in the field. The investigator is encouraged to describe how the proposed work would ultimately impact the quality of life of CML patients and their families. If this proposal is duplicative of a proposal submitted to another FY04 CDMRP program announcement, provide a strong justification for submitting duplicate proposals and the proposal's relevance to CML.

5. Main Body: Start section on a new page; 20-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. It is the investigator's responsibility to clearly articulate how the proposed research is innovative. The inclusion of preliminary data **is required** for all Therapeutic Development Award proposal submissions. Investigators must submit promising and well-founded preliminary data relevant to CML and the proposed project.

Describe the proposed project using the general outline provided below:

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

b. Rationale: State the purpose of the study and the expected results.

c. Objectives: State concisely the specific aims and a plan for how the project will be executed.

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

e. Methodology: Describe the experimental design and methodology, including statistical analysis as appropriate.

f. Innovation: State concisely how the concept is innovative and how it relates to the current state of knowledge in the area.

g. Product: Describe the projected product(s) and utility and impact on therapeutics development in CML.

6. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used.

7. 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).

8. Biographical Sketches: Three-page limit per individual. Biographical sketches should be included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower priority scores. The Biographical Sketch form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

9. Existing/Pending Support: Start section on a new page; 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 PI and key personnel. If no support exists, state "none." Proposals submitted under this program announcement should not duplicate other funded research projects.

10. 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 purchase or available for use at no cost to the USAMRMC. Indicate if government-owned facilities or equipment are proposed for use.

11. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit. Include an appropriately titled page listing the documents you have included in this section.

12. Publications and/or Patent Abstracts: Five-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.

13. Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. **This section is not for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other relevant information needed to judge the proposal.** Unrequested material that is submitted may be construed as an attempt to gain a competitive advantage and will be removed; it may be grounds for administrative rejection of the proposal.

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

- Provide letters of support from any collaborating individuals or institutions in this section of the proposal.

If a consortium is proposed, provide:

- Letters of collaboration from all academic institutions and/or private sector participants, as appropriate, documenting a willingness to participate and demonstrating that a multi-institutional, multidisciplinary team of investigators is participating in the project, that the necessary drugs, modalities, or technologies are available, and that there is no unnecessary duplication of resources.

- Letters of support from authorized officials at each of the participating investigators' institutions documenting their support to the consortium.
- Documentation that the participating institutions and investigators have an intellectual property plan, and that the individuals and their institutions are willing to resolve intellectual property issues.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the submitted proposal.

F. Budget Information: Budget Information includes the Detailed Cost Estimate form and Justification. Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

1. Funding Restrictions: Although there are no total dollar amount restrictions to these awards, programmatic priority will be given to smaller-scale, cost-efficient projects with well-defined endpoints. Funding can be requested for up to 3 years. Direct costs can cover salary, expenses including research supplies, and travel to scientific meetings. The amount for travel may not exceed $1,800 per year per investigator. Institutional support and commitment must be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. If a biotechnology or pharmaceutical company applies for this mechanism as an individual submitter or as a part of a consortium, the company is expected to leverage its own resources to complement the funding provided for the study by this award. For proposals involving a consortium, direct costs can also cover expenses for meetings that bring together members of the consortium.

2. Detailed Cost Estimate Forms and Justifications Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided for expenses in all categories. The Detailed Cost Estimate form and Justification for your proposal must be uploaded as a PDF file, separate from the proposal.

The following section provides instructions for preparing the Detailed Cost Estimate form. All amounts entered should be in U.S. dollars.

a. Personnel:

i. Name: Starting with the PI, 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 PI of the proposal.

ii. 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.

iii. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The 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%, 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.

iv. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project.

v. Percentage of Effort on Project: The qualifications of the PI 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.

vi. Salaries 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.

vii. 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 for all sponsors. Documentation to support the fringe benefits should be provided.

viii. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

b. Consultant Costs: Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants.

c. 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 non-profit organizations, such approved cost elements shall be separately negotiated. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed $5,000.

d. 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, 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. If human cell lines are to be purchased, state the source and the description.

e. Travel Costs: Travel costs may not exceed $1,800 per year per investigator.

f. 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 USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

g. Other Expenses: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide 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.

h. Subaward 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:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- 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;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.

i. 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.

j. 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. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should agree with the amount previously entered online in the Proposal Information https://cdmrp.org/proposals.

3. 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.

G. Regulatory Requirements: Completed and signed copies of the "Certificate of Environmental Compliance" and "Principal Investigator Safety Program Assurance form" must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other regulatory documents (Research Involving Human Subjects and/or Anatomical Substances; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

H. USAMRAA Documents: The most current version of the institution's negotiated "Rate Agreement," the "Certifications and Assurances for Assistance Agreements," and the "Representations for Assistance Agreements" must be uploaded by the Contract Representative from the Sponsored Programs Office (or equivalent). These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system prior to negotiations.

I. Submission Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by the deadline. If your proposal is either incomplete or not approved electronically before the deadline, it will not be considered for review. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time **July 27, 2004** deadline.

The timeline for Therapeutic Development Awards is:

Online Letter of Intent:	Expected by June 29, 2004
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time July 27, 2004**
Peer Review:	September 2004
Programmatic Review:	November 2004
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after programmatic review
Award Start Date:	Between February 2005 and September 2005

J. Electronic Submission Requirements: Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at https://cdmrp.org/proposals.

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time July 27, 2004 deadline.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Detailed Cost Estimate form and the Justification form. Budget Information must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview:

1. Process: The CDMRP uses a two-tiered review process for proposal evaluation. 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 scientific merit as well as overall program goals.

2. Peer Review: Peer review is conducted by panels organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals, based upon the review criteria published for each award mechanism.

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting scientific review administrator. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the 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 below). 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 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 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.

3. 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 scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to maintain 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 primarily use the peer review summary statements and the proposal abstracts. SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

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. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI submissions will be based upon scientific excellence and program relevance.

B. Review Criteria:

1. Peer Review: Therapeutic Development Award proposals will be evaluated according to the following criteria:

- **Research Strategy:** Does the applicant provide preliminary data that support the approach and scientific rationale for the technological/product development or hypothesis? Are the conceptual framework, design, methods, and analyses adequately developed and well integrated to support the feasibility, aims, and promise of the approach? For product-driven research, is the experimental design sound and well developed with sufficient statistical power (as appropriate) to lead to proposed products? For hypothesis-driven research, is the experimental design sound and well developed with sufficient statistical power (as appropriate) to lead to proposed results? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Does the study have clear product-driven endpoints?

  If appropriate,

  - Are the screening assays and preclinical models to be developed, modified, and/or validated for screening or testing of small molecule(s) suitable for identification and/or pharmacological/pharmokinetic assessment of agents or modalities with therapeutic potential for CML?
  - Are the outlined chemical synthetic pathways for modification of lead compounds or the formulation of potential delivery systems of modalities based in rational design?
  - Does the proposed pilot large-scale production adhere to GMP standards and provide sufficient quantities of product for future studies?
  - Are the protocols designed for ADMET testing suitable for the elucidation of data necessary for the advancement of the agents and/or modalities to IND application?
  - Does the proposal detail a suitable plan for generating the scientific data needed for an IND application?

- **Therapeutic Relevance:** For product-driven research, what will be the effect of the proposed products on clinical application of therapeutics in CML? For hypothesis-driven research, what will be the effect of these studies on the concepts or methods that drive therapeutic development? Does this study address a critical and/or underserved problem in CML therapeutic development? Does the applicant make a convincing case for the relevance of the study to the discovery, assessment, and/or development of CML therapeutics? Is evidence provided for the predictive clinical value of the research? How does this research advance the agenda of bringing CML-specific therapies to clinical trials?

- **Disease Relevance:** Does the proposal make a convincing case for the relevance of the research to CML? If agents are being screened or tested, how relevant are they to CML or delivery of CML therapeutics? If models are being developed, modified, and/or validated, do they accurately reflect the molecular, cellular, and/or systemic biology of CML? Do proposed IND application(s) address specificity to CML? To what extent will the project, if successful, make an original and/or important contribution to the goal of eradicating CML? Has the investigator described how the proposed work would ultimately impact the quality of life of CML patients and their families?

- **Innovation:** Is the proposed project and/or product innovative in research methods or technologies, clinical interventions, adaptations of existing methods or technologies, or in other ways? Does the project propose new paradigms, challenge existing paradigms, or address underexplored or unexplored areas? Is the project one for which innovation is not necessary?

- **Principal Investigator and Personnel:** Is the PI appropriately trained and well suited to carry out this work? Are the other scientific personnel well qualified to participate in the project and develop the products? Is there appropriate representation from all areas of expertise needed to conduct the study and develop the products successfully? **If a consortium is proposed**, is the team appropriate for addressing the proposed project and develop the products? Are letters of collaboration provided for any proposed collaborative arrangements?

- **Environment:** Is there evidence that the scientific environment and proposed collaborative arrangements adequately support the development of the product(s)? Is there evidence of institutional support for all personnel provided with the proposal? **For proposals involving consortia:** Is there evidence that the consortium is goal-focused? Is there adequate synergy between and among the involved institutions/organizations? Is there a clear plan for interaction between and among members of the consortium? Is there a clear description of the plan for sharing and evaluating data in real time between and among members of the consortium? Do the institutions/organizations involved in the project strengthen the proposal? Is there evidence of an intellectual property management plan that is agreed upon by all participating institutions? Have the institutions involved provided assurance of cooperation to remove institutional barriers to ensure the successful establishment and maintenance of the consortium as a whole?

- **Budget:** Is the budget appropriate for the project proposed? If appropriate, is there a clear and fair description of the distribution of funds among members of the consortium? Is appropriate cost sharing for major equipment delineated?

- **Product:** Is the proposed method, model, agent, or other product specific for CML? Does the product address underdeveloped or novel critical needs in clinical agent development and/or therapeutics in CML? Does the product significantly advance the development of new therapeutics for CML? For product-driven research, will the products provide tools necessary for the identification and assessment of agents specific for potential CML therapeutics and/or provide novel therapeutics with direct clinical application for CML? For hypothesis-driven research, are the products truly innovative, not merely incremental advances of known pathways?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to maintain the CMLRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation; and
- Program portfolio balance.

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.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tiered evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in December 2004.

B. Administrative Requirements: All awards are made to organizations, not individuals. A PI 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. 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 and DOD Grant and Agreement Regulations). Any organization requesting receipt of an award from this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.

Any change in the institution, the PI, and/or the SOW will require that the PI resubmit contact information. Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the proposed SOW and associated budgets may be required.

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

D. Regulatory Review:

1. Overview: Concurrent with the USAMRAA negotiations, the office of Surety, Safety and Environmental will review the Certificate of Environmental Compliance, and Principal Investigator Safety Program Assurance form submitted with the proposal. The USAMRMC RCQ office will review documents related to Research Involving Animal Use and Research Involving Human Subjects/Anatomical Substance Use submitted upon request to ensure that Army regulations are met.

2. Certificate of Environmental Compliance: The Certificate of Environmental Compliance must be submitted with the proposal. If multiple research sites/institutions are funded in your proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

3. Safety Program Documents: The Principal Investigator Safety Program Assurance form must be submitted with the proposal.

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at http://mrmc-www.army.mil/crprcqsohdfsplan.asp. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of

the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc.

If multiple research sites/institutions are funded in your proposal, then a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

4. Research Involving Animal Use: Please note, each award mechanism has specific requirements regarding human subjects and animal use. Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc.

5. Research Involving Human Subjects/Anatomical Substances: Please note, each award mechanism has specific requirements regarding human subjects and animal use. Human Subjects and/or Anatomical Substances use documents should not be submitted with the proposal and will be requested at a later date. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC RCQ office. 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. For example:

- Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the 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.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects and/or anatomical substances can be found at http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf. An informed consent form template can be located at http://mrmc-www.army.mil/docs/rcq/consentform_template.pdf.

6. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or use of laboratory animals without express written approval from the applicable USAMRMC RCQ office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs office (or equivalent).

E. Reporting: All research awards will require the timely delivery of several reports during the research effort. Reporting requirements consist 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.

VIII. OTHER INFORMATION

A. Disclosure of Proprietary Information outside the Government: By submission of a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or utilized. Funded proposals 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.

B. 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 who, 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.

C. 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.

D. 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 CDMRP 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.

E. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq.[2]), 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.

F. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

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

IX. ACRONYM LIST

ADMET	Adsorption, Distribution, Metabolism, Excretion and Toxicity
AVI	Audio Video Interleave
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CML	Chronic Myelogenous Leukemia
CMLRP	Chronic Myelogenous Leukemia Research Program
DOD	Department of Defense
FY	Fiscal Year
GMP	Good Manufacturing Practice
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IND	Investigational New Drug
IRB	Institutional Review Board
IP	Integration Panel
M	Million
MPEG	Moving Picture Experts Group
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SOW	Statement of Work
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
TDA	Therapeutic Development Award
WAV	Wave