

Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

The Clinical Translational Research Award is designed to sponsor innovative research that will result in substantial improvements over current approaches to breast cancer chemoprevention and therapy by accelerating the progression of recent, highly promising findings in preclinical breast cancer research from the laboratory to the clinic. These awards are intended to support both new and established scientists across a broad spectrum of disciplines. Partnerships between academic institutions and biotechnology companies are encouraged. *Clinical Translational Research Award proposals are being sought only in the areas of chemoprevention and therapeutics.*

Successful applicants must initiate a prospective clinical trial and accrue participants for a minimum of 1 year during the award period. They must also include preliminary data to support the feasibility of their hypotheses and approaches. This award is not intended to support early drug discovery or development, correlative studies, or the study of new combinations of standard breast cancer therapies.

Funding for these awards may be requested for up to 5 years. No dollar amount restrictions have been established for these awards.

A. Title of Award: Clinical Translational Research Award (CTR).

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: BC05-CTR.

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 may be addressed to the CDMRP at:

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-ZB-C (BC05-CTR)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

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

Website: <https://cdmrp.org/> (User's Guide located in upper right corner of 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 Address to Access Application Package: Proposals must be submitted electronically at <https://cdmrp.org/>. The website contains all the information, forms, documents, and links needed to apply.

I. 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/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the applied-for written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

The Clinical Translational Research Award is designed to support innovative breast cancer research that offers the potential to revolutionize the practice of breast cancer prevention and treatment. Applicants must include preliminary data to support the feasibility of their hypotheses and approaches and a plan to conduct a prospective clinical trial or study during the award period.

For FY05, Clinical Translational Research Award proposals are only being sought in the areas of chemoprevention and therapeutics.

This award is not intended to support early drug discovery or development, correlative studies, or the study of new combinations of standard breast cancer therapies.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately \$20 million (M) is available to fund FY05 BCRP Clinical Translational Research Awards.
- It is anticipated that approximately 10 proposals will be funded, depending on the number and quality of the applications.
- Funding for Clinical Translational Research Awards can be requested for up to 5 years. These awards have no dollar amount restrictions.
- Investigators funded by the Clinical Translational Research Award mechanism will be required to meet with USAMRMC contracting and grants officers during award negotiations to develop a timeline covering the full period of performance. Continued funding under this award mechanism will be contingent upon achieving study milestones in accordance with this timeline.

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. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see “Major Equipment” located in Subsection VII.G.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 HBCU/MI, and administrative compliance issues.

V. PRE-PROPOSAL PREPARATION, PROPOSAL PREPARATION, AND SUBMISSION INFORMATION

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

B. Pre-proposal Preparation: Investigators interested in applying for Clinical Translational Research Awards must submit Proposal Information and a pre-proposal; see Section V of the Full Text of the Program Announcement for preparation instructions. Pre-proposals will be reviewed as described in Section VI of the Full Text of Program Announcement.

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

C. Pre-Proposal Submission Date and Time: Pre-proposal Deadline: April 5, 2005, 5:00 p.m. Eastern time. Pre-proposals must be submitted through the CDMRP eReceipt system.

D. Invited Proposal Preparation: Pre-proposals will be screened by the BCRP Integration Panel to determine those projects that best fulfill the intent of the award mechanism. Invitations to submit full proposals will be sent to selected applicants no later than May 2005. **Do not submit a full Clinical Translational Research Award proposal unless you receive a letter of invitation.**

All proposals must be converted into an electronic PDF file for electronic proposal submission. Please see the Full Text of Program Announcement for details.

E. Proposal Contacts: The Proposal Contacts **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 institution. The Proposal Contacts must be “Finalized” for approval by the applicant’s Sponsored Programs Office’s (or equivalent) representative.

F. Invited Proposal Submission Date and Time: Full Proposal Deadline: July 26, 2005. 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.

G. Electronic Submission Requirements: Electronic submission is required. No paper copy submissions will be accepted. Pre-proposals and full proposals must be submitted electronically at <https://cdmrp.org/>. Please see the Full Text of the Program Announcement for details.

VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tier 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 the Program Announcement.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements including regulatory 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 the Program Announcement.

Funding for the CTR Awards will be disbursed in installments. The first installment will be made at the time of the award; subsequent installments will be contingent upon the successful completion of milestones. Milestones from the approved Statement of Work will be determined during the award negotiation process. *Failure to complete each milestone may result in forfeiture of the subsequent installment of CTR Award funding.*

B. Reporting Requirements: Annual reporting requirements apply.

Full Text of Program Announcement

I. GENERAL INFORMATION

The Clinical Translational Research Award is designed to sponsor innovative research that will result in substantial improvements over current approaches to breast cancer chemoprevention and therapy by accelerating the progression of recent, highly promising findings in preclinical breast cancer research from the laboratory to the clinic. These awards are intended to support both new and established scientists across a broad spectrum of disciplines. Partnerships between academic institutions and biotechnology companies are encouraged. ***Clinical Translational Research Award proposals are being sought only in the areas of chemoprevention and therapeutics.***

Successful applicants must initiate a prospective clinical trial and accrue participants for a minimum of 1 year during the award period. They also must include preliminary data to support the feasibility of their hypotheses and approaches. This award is not intended to support early drug discovery or development, correlative studies, or the study of new combinations of standard breast cancer therapies.

Funding for these awards may be requested for up to 5 years. No dollar amount restrictions have been established for these awards.

A. Title of Award: Clinical Translational Research Award (CTR)

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: BC05-CTR.

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-ZB-C (BC05-CTR)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

2. Questions related to electronic 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 301-682-5507 and is also provided on the Web. Other help desk contact information is:

Website: <https://cdmrp.org/> (User's Guide located in upper right corner of 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: ga.baa@det.amedd.army.mil
Mail: Director
US Army Medical Research Acquisition Activity
ATTN: MCMR-ZB-A
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/>. This website will contain all the information, forms, documents, and links needed to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

I. 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/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the applied-for written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Clinical Translational Research Award is part of the DOD BCRP, which was established in FY92 to promote innovative research directed toward the eradication of

breast cancer. Appropriations for the BCRP since FY92 total \$1.68 billion (B). The FY05 appropriation is \$150 million (M). Of this, approximately \$20M will be available for Clinical Translational Research Awards.

B. Program Objectives: The overall goal of the FY05 BCRP is to promote research focused on eradicating breast cancer. Therefore, the BCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. The BCRP focuses its funding on innovative projects, particularly those involving multidisciplinary and/or multi-institutional collaborations and alliances, with the potential to make a significant impact on breast cancer. Under-investigated avenues of research and novel applications of existing technologies are strongly encouraged. The BCRP encourages risk-taking research; however, such projects must demonstrate solid scientific judgment and rationale.

Within this context, the BCRP's objective is to fund a balanced portfolio of scientifically meritorious research related to all aspects of breast cancer. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiologic research, including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; ethics; and economics. Proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are strongly encouraged.

C. Award Mechanism Description: The Clinical Translational Research Award builds on recent, highly promising discoveries in breast cancer research that offer the potential to revolutionize breast cancer prevention and/or treatment. The focus of the Clinical Translational Research Award should be on the clinical trial and work leading to the clinical trial. *For FY05, Clinical Translational Research Award proposals are being sought only in the areas of chemoprevention and therapeutics.*

Clinical Translational Research Awards support projects that are likely to have a major impact on breast cancer chemoprevention and/or therapy by applying promising and well-founded laboratory or other preclinical or clinical research findings to the treatment of patients with, or populations at risk for, breast cancer. Applicants may have originated projects in their laboratories that will form the basis for clinical trials to be conducted during this award. Projects also may capitalize on independently published research, although this is rare. Finally, proposed projects may leverage chemopreventive or therapeutic technologies from partnerships with biotechnology companies *if* the applicant can demonstrate the ability to conduct the required preclinical and Phase 1 or 2 clinical trial.

This award is not intended to support early drug discovery or development, correlative studies or studies of new combinations of standard breast cancer therapies.

Applicants must include preliminary data to support the feasibility of their hypotheses and approaches and a plan to conduct a prospective clinical trial or study during the course of the award. Proposals also must include a clear experimental and, a properly powered statistical plan, as appropriate, to perform a prospective clinical trial, as well as information demonstrating

that participants will be accrued to the proposed clinical trial for a minimum of 1 year during the award period.

These awards are intended to support both new and established scientists across a broad spectrum of disciplines. Partnerships between academic institutions and biotechnology companies are encouraged. Ultimately, the Clinical Translational Research Award mechanism is designed to sponsor innovative research that will result in substantial improvements over current approaches to breast cancer chemoprevention and therapy.

Participating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation. An intellectual and material property plan agreed to by all participating institutions is required in the proposal's administrative documentation (see Subsection VII.F.12).

III. AWARD INFORMATION

These awards have no dollar amount restrictions. Research should be completed within 5 years. The focus of the Clinical Translational Research Award should be on the clinical trial and the work leading to it. Funding will be disbursed in installments. The first installment will be made at the time of the award; subsequent installments will be contingent upon the successful completion of specific milestones. Milestones from the approved Statement of Work will be determined during the award negotiation process. *Failure to complete each milestone may result in forfeiture of the subsequent installment of Clinical Translational Research Award funding.*

The allotment for travel is \$1,800 per year per PI to attend scientific or technical meetings. Additional funding also should be requested for the PI to attend two 3½-day Era of Hope meetings to disseminate the results of the DOD-sponsored research.

It is the policy of the DOD that the Principal Investigator (PI) should possess the equipment needed to support the proposed research; requests for equipment in excess of 10% of the direct costs of the project will be considered only in rare cases.

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. The CDMRP expects to allot approximately \$20M of the \$150M FY05 BCRP appropriation to fund approximately 10 Clinical Translational Research Awards, depending on the quality and the number of proposals received.

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. Agencies of local, state, and federal governments are eligible to the extent that

proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under “Major Equipment” in Subsection VII.G.2.c of the Full Text of Program Announcement.

D. Other Eligibility Criteria

1. Duplicate Submissions: Submission of the same research project to the BCRP under different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

2. Historically Black Colleges and Universities/Minority Institutions (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 on 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 at <http://cdmrp.army.mil/spp> under Minority Institutions.

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:

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.
- Margins are less than 0.5 inches on any side.
- Proposal body exceeds page limit.
- Proposal body is missing.
- Required administrative documentation is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.

¹Executive Orders 12876, 12900, and 13021

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

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

V. PRE-PROPOSAL PREPARATION AND SUBMISSION INFORMATION

Investigators interested in applying for the Clinical Translational Research Award must submit a pre-proposal. Pre-proposals will be screened to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Clinical Translational Research Award proposal will be sent to selected investigators no later than May 2005. **Do not submit a full Clinical Translational Research Award proposal unless you receive a letter of invitation.**

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

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of Part 1 for which information is entered as data fields.
- **Pre-proposal:** The pre-proposal is uploaded as a PDF (Portable Document Format) file under the “Proposal Information” tab.

B. Proposal Information: Applicants are required to submit the Proposal Information (Part 1) prior to upload of the pre-proposal. Complete the Proposal Information as described in <https://cdmrp.org/>. The Proposal Information must include the e-mail address of a representative from the applicant’s Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution.

- **Letter of Intent:** A Letter of Intent is not necessary for pre-proposal submission for the Clinical Translational Research Award.

C. Pre-proposal Preparation

1. Format: All pre-proposals must be converted into a single electronic PDF file for electronic submission. Pre-proposals must be uploaded under the “Proposal Information” 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 pre-proposals for PDF submission, the instructions in this subsection must be followed carefully. Please note that pre-proposals do not require approval by the Contract Representative of the applicant’s institution’s Sponsored Programs Office (or equivalent).

Please Note New Format Requirements

The pre-proposal must be clear and legible and conform to the following guidelines.

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inches in all directions.**
- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

Failure to follow the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to peer review.

- **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, but applicants should keep in mind that 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.
- **Language:** English.

2. Pre-proposal Title/Referral Page: No page limit. Complete the [Title/Referral Page](#). Complete each section as described:

- a. Pre-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. PI's full name (first, middle initial, last).
- d. Submitting Institution
- e. Award mechanism: Type in "Clinical Translational Research Award."
- f. Keyword descriptive technical terms: To assist the staff in assigning pre-proposals to the appropriate reviewers, please specify the subject area of the proposal. Also, please list specific keywords and descriptive technical terms that best describe the project's technical aspects.

- g. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the pre-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 reviewing this pre-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. Pre-proposal Translatability Statement: Start section on a new page; one-page limit. Specify how the proposed work will be translated into the clinic, i.e., how it will result in a prospective clinical trial with at least 1 year of patient accrual during the course of the award. Articulate how the proposed work will further the BCRP's goals and meet the intent of the Clinical Translational Research Award mechanism.

4. Pre-proposal Body: Start section on a new page; two-page limit. The PI is responsible for clearly articulating how the proposed research meets each of the screening criteria for pre-proposals:

- The proposed project applies innovative, yet well-founded laboratory or other preclinical insights that justify the progression of the project into a clinical trial, with emphasis on its potential to revolutionize chemoprevention and/or therapy of breast cancer.
- The pre-proposal outlines a *clear* experimental plan for a prospective human clinical study or trial that will be conducted during the course of the award. Clinical research funded by this award can result from:
 - The development in the investigator's or collaborator's laboratory of a new compound that can enter Phase 1 testing.
 - Independently published or unpublished preclinical and/or clinical data to support the conduct of a Phase 1 or 2 breast cancer trial. In this case, the investigator must present sufficient preliminary data to demonstrate his or her ability to conduct the required preclinical and clinical studies.
 - A partnership with a biotechnology (or other) company that provides a novel, highly promising new agent for the chemoprevention or therapy of breast cancer.
- When appropriate, the pre-proposal outlines a *clear*, appropriately powered statistical plan to answer the research questions posed.
- Evidence supports the likelihood of accruing study subjects in the proposed prospective trial for a minimum of 1 year.
- The project's results have the potential to revolutionize breast cancer chemoprevention and/or therapy.

5. References: Start section on a new page; one-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).

6. Biographical Sketches: Four-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 global 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.

D. Electronic Pre-proposal Submission Requirements: Electronic submission of the pre-proposal is required. Pre-proposals will be accepted only as a single PDF file submitted through the CDMRP eReceipt system at <https://cdmrp.org/>. Pre-proposals must be submitted on the CDMRP eReceipt system by the 5:00 p.m. Eastern time April 5, 2005 deadline.

Several steps are critical to successful pre-proposal submission.

- The Proposal Information must be submitted prior to submission of the pre-proposal. Applicants are encouraged to begin this part of the submission process early. During the full proposal submission process you will have an opportunity to edit the Proposal Information as needed.
- Although the applicant's Sponsored Programs Office (or equivalent) is not responsible for any part of pre-proposal submission, the Sponsored Programs Office (or equivalent) will be responsible for portions of the full proposal submission. Therefore, applicants are encouraged to begin coordinating with their Sponsored Programs Office (or equivalent) early, well in advance of full proposal submission.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time April 5, 2005 pre-proposal deadline.
- All components of the pre-proposal must be incorporated into one PDF file prior to upload.
- Some items to be included in the pre-proposal may need to be scanned. All scanned documents, including figures, should be scanned at a resolution of 300-400 dpi or less.

VI. PRE-PROPOSAL SCREENING INFORMATION

Pre-proposals will be screened according to the criteria listed in Subsection V.C.4 to determine those projects that best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Clinical Translational Research Award proposal will be sent to selected investigators no later than May 2005.

VII. INVITED 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. *Do not submit a full Clinical Translational Research Award proposal unless you receive a letter of invitation.*

The 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 not necessary for the Clinical Translational Research Award.
- **Proposal Contacts:** Contact information for both the PI and the Contract Representative is required to complete the proposal submission process.
- **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 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.

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

- **The Contract Representative’s Contact Information Profile: This must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA) Required Documents:** The institution’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 (or equivalent) must provide approval of all proposal components (Proposal Information, Proposal Contacts, 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 26, 2005. 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>. The Proposal Information may be “Verified & Saved” for editing purposes until “Submit Final” for approval by their Sponsored Programs Office’s (or equivalent’s) representative.

- **Letter of Intent:** An electronic Letter of Intent is not required for the Clinical Translational Research Award.

C. Proposal Contacts: The Proposal Contacts **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 institution. The Proposal Contacts must be “Finalized” for approval by the applicant’s Sponsored Programs Office’s (or equivalent) representative.

D. 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 period for which the USAMRMC will provide financial support.

Specific milestones from the approved Statement of Work will be determined during the negotiation process. Funding will be disbursed in installments contingent upon the successful completion of these milestones. For this reason, applicants are encouraged to include specific and measurable goals in their SOW.

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 being sure to include the following:
 - Time required to prepare and submit clinical protocols;
 - Time required to obtain the necessary regulatory approvals (both local IRB and HSRRB);
 - Time required to apply for and obtain Investigational New Drug (IND) status, if appropriate;
 - Time required for patient recruitment and accrual.
- Indicate the numbers of research subjects (animal or human) projected or required for each task,
- Identify methods, and
- Identify outcomes, products, and deliverables for each phase of the project.

E. 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 on the Integration Panel’s review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the PI submit abstracts that describe the proposed work in full detail.

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 the specific aims of the study concisely.
- **Study Design:** Describe the study design briefly.
- **Relevance:** Provide a brief statement explaining the relevance of the proposed work to the Program’s goals. For example, describe how the study will cure, prevent, or improve the detection or treatment of breast cancer.

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 be the ultimate applicability of the research?

- 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?

F. Proposal

1. Format: All proposal components (proposal body, biographical sketches, publications, letters of support, etc.) must be converted into a single 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. Please note that proposals not adhering to these regulations will be withdrawn prior to peer review.

Please Note New Format Requirements

The proposal must be clear and legible and conform to the following guidelines.

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inches in all directions.**
- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

Failure to follow the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to peer review.

- **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, but applicants should keep in mind that 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.
- **Language:** English.

2. Title/Referral Page: No page limit. Complete the [Title/Referral Page](#). Please note that all forms are available on the “Summary Tab” of eReceipt. Complete each section 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. PI’s full name (first, middle initial, last).
- d. Submitting Institution.
- e. Award mechanism: Type in “Clinical Translational Research Award.”
- f. 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.
- g. 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 that 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, her or his 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. Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

4. Proposal Relevance Statement: Start section on a new page; one-page limit. State explicitly how the proposed work is innovative, translational, meets the intent of the Clinical Translational Research Award mechanism, and is relevant to breast cancer chemoprevention and/or therapeutics. *Note that for Clinical Translational Research Awards, the Proposal Relevance Statement will be available for programmatic review.*

5. Main Body: Start section on a new page; 15-page limit including any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. Clinical Translational Research Award proposals must include promising preliminary data relevant to the proposed project. The PI is responsible for clearly articulating the ways in which the proposed research is innovative.

Describe the proposed project using the following outline:

- a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Explain why and how the proposed laboratory advancement should proceed to a clinical trial. Describe previous experience most pertinent to the proposal. Cite relevant literature references.
- b. **Hypothesis/Rationale/Purpose:** State the hypothesis to be tested and the expected results.
- c. **Objectives:** State concisely the study's specific aims and research strategy.
- d. **Preliminary Data:** Provide pertinent data to support the hypothesis to be tested.
- e. **Proposed Research and Methods:** Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Discuss plans for the prospective human clinical trial. If the methodology is new or unusual, provide sufficient details for evaluation.

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: Four-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 global 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. 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. The following documentation must be included in the Clinical Translational Research Award proposal submission:

- Letters of support documenting the availability of and quality control for all critical reagents
- Letters of support from any collaborating individuals.
- Documented evidence that all participating institutions have an intellectual and material property plan and are willing to resolve intellectual and material 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.

13. 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.

G. Budget Information: Budget Information includes the [Detailed Cost Estimate form and Budget Justification form](#). Budget Information is uploaded under the “Required Files” tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for Clinical Translational Research Awards can be requested for up to 5 years. These awards have no dollar amount restrictions. The allotment for travel is \$1,800 per year per investigator to attend scientific/technical meetings.

Additional funding must also be requested for the PI to attend two 3½-day Era of Hope meetings to disseminate the results of the DOD-sponsored research.

Funding for the Clinical Translational Research Awards will be disbursed in installments. The first installment will be made at the time of the award; subsequent installments will be contingent upon the successful completion of specific milestones. Milestones from the approved Statement of Work will be determined during the award negotiation process. *Failure to complete each milestone may result in forfeiture of the subsequent installment of the Clinical Translational Research Award funding.*

2. Detailed Cost Estimate Form and Budget Justification Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. **Organizations must provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.** The Detailed Cost Estimate form and Budget Justification for the proposal must be uploaded as a PDF file, separate from the proposal.

Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (<http://farsite.hill.af.mil>), Contract Cost Principles and Procedures.
- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

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 Budget 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 Budget 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, please 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 to scientific/technical meetings may not exceed \$1,800 per year per investigator. Additional funding must also be requested for the PI to attend two 3½-day Era of Hope meetings to disseminate the results of the DOD-sponsored research.

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 Direct Costs: 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 Budget 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 equal the amount previously entered online in the Proposal Information at <https://cdmrp.org/>.

3. Budget Justification (third page of the Detailed Cost Estimate form): Each item in the budget should be clearly justified in the Budget Justification section of the Detailed Cost Estimate form.

H. 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/Cadavers; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

I. USAMRAA-Required 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.

J. Submission Date and Time: 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 26, 2005 deadline.

The timeline for the Clinical Translational Research Award is:

Pre-Proposal Submission Deadline:	5:00 p.m. Eastern time April 5, 2005
Pre-proposal Screening:	Early May 2005
Full Proposal Invitations:	May 2005
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time July 26, 2005
Peer Review:	September 2005
Programmatic Review:	November 2005
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:	Anticipated between December 2005 and September 2006

K. 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/>.

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.
- Proposal Contacts must be submitted prior to submission of the proposal. The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- 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 26, 2005 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 Budget 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.

VIII. INVITED PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier 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 on 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 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. *Note that for CTR Awards, the Proposal Relevance Statement will be available for programmatic review.* 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 on scientific excellence and program relevance.

B. Review Criteria

1. **Peer Review:** Clinical Translational Research Award proposals will be evaluated according to the following criteria:

- **Clinical Relevance and Impact:** Is the project likely to extend recent findings in breast cancer research that offer the potential to revolutionize the practice of breast cancer prevention and/or treatment? Does the study address an important problem related to the chemoprevention and/or therapy of human breast cancer? If the aims of the application are achieved, are they likely to have a *substantial clinical impact*?
- **Translational Potential:** *Is the project likely to result in a minimum of 1 year of subject accrual?* Does the project clinically evaluate promising, well-founded laboratory or other preclinical research findings for the treatment of patients with, or populations at risk for, breast cancer? Does the project directly link laboratory and other preclinical findings and the prospective clinical trial? Does the research have the potential to produce substantial improvements over today's approaches to the chemoprevention and/or therapy of breast cancer?
- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses (including laboratory and other preclinical evidence) adequately developed and integrated to support the clinical feasibility and promise of the approach? Does the prospective clinical trial address the impact on chemoprevention and/or therapy within the grant period? Does the applicant acknowledge potential problem areas and consider alternative approaches? Does the applicant demonstrate the ability to accrue a sufficient number of subjects?
- **Innovation:** Does the research employ *novel* concepts, agents, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new, underexplored, or unexplored areas?
- **Statistical Plan:** Is the design of the clinical trial sound and sufficiently well developed, with the statistical power required to lead to meaningful results? Is a clear statistical plan provided, including power analysis, if appropriate? Is the appropriate statistical expertise represented on the research team?
- **Personnel:** Is the PI trained appropriately and well suited to carry out this work? Are the other scientific personnel qualified to participate in the project? Are all the areas of expertise needed to conduct the study successfully well represented?
- **Environment:** Is the scientific/clinical environment an appropriate setting for the proposed research? Is the proposed preclinical and clinical research adequately supported by the scientific environment, necessary resources, and proposed collaborative arrangements? Is evidence of institutional support provided? Does the proposal describe an intellectual and material property management plan agreed on by all participating institutions?
- **Budget:** Is the budget appropriate for the research proposed?

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 BCRP'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;
- Program portfolio balance; and
- Adherence to the intent of the award mechanism.

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.

IX. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tier 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 November 2005.

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 institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for the 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 (OMB 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, PI, and/or 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.

The government strongly discourages transferring any award that includes a Phase I, Phase II, or Phase III clinical trial. Should the PI move to another institution, the government reserves the right to approve the assignment of a new PI to the award.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist and/or representative 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 and project milestones will be determined during the negotiation process.

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiations, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver 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 <https://mrmc.detrick.army.mil/crprcsohdfspplan.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 <https://mrmc.detrick.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: 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 <https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: (See Subsection VII.H for information pertaining to the submission of human subjects and/or human anatomical substances or cadavers documents.) For planning purposes, please be advised that in addition to local IRB approval to conduct research involving human subjects and/or anatomical substances or cadavers, a second tier of IRB review and approval is also

required by the DOD. This second review is conducted by the HSRRB, which is administered by the USAMRMC Office of Research Protections (formerly Regulatory Compliance and Quality). 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. Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-sponsored research. Title 10 United States Code 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual’s legally authorized representative must be obtained prior to the individual’s participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators 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.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at

[https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix\(13May04\).doc](https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc).

An informed consent form template can be located at

<https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc>.

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/cadavers, or laboratory animals without written approval from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the applied-for written approvals directly to the applicant.

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

1. Research Progress Report Requirements: 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. Each report must

describe progress toward achieving the milestones listed on the USAMRMC-approved timeline. Continued funding under this award mechanism is contingent upon timely achievement of study milestones. *Failure to submit timely progress reports may result in a delay in or termination of award funding.*

2. Fiscal Report Requirements: Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

X. 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 used. 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

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

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.

XI. ACRONYM LIST

AVI	Audio Video Interleave
BCRP	Breast Cancer Research Program
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CTR	Clinical Translational Research Award
DOD	Department of Defense
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MB	Megabytes
MPEG	Moving Picture Experts Group
OMB	Office of Management and Budget
PDF	Portable Document Format
PI	Principal Investigator
SOW	Statement of Work
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave