Program Announcement

I. GENERAL INFORMATION

This program announcement is being released prior to the receipt of Federal funds appropriated in a bill for this program; funding of proposals received in response to this program announcement is contingent on the receipt of these funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: Breast Cancer Research Program (BCRP) Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Partnership Training Award.

B. Program Name: Department of Defense (DOD) Fiscal Year 2006 (FY06) BCRP.

C. Funding Opportunity Number: W81XWH-06-BCRP-HPT.

D. Agency Name: 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 announcement, 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@amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-ZB-C (BC06-HPT) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help is also available on the CDMRP website or by e-mail as follows:

Website:	https://cdmrp.org (User's Guide located in upper right corner of the proposal submission website)
E-mail:	help@cdmrp.org

F. Anticipated Instrument Type(s): The USAMRMC executes 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@amedd.army.mil
Mail:	Director US Army Medical Research Acquisition Activity ATTN: MCMR-AAA-R 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 at https://cdmrp.org. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulty in downloading documents should contact the CDMRP as indicated in Subsection I.E.2.

I. Award/Regulatory Approval: The applicant may not use, employ, or subcontract for the use of any human subjects, human biological substances, cadavers, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the USAMRMC.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The HBCU/MI Partnership Training Award is one of the mechanisms of the Breast Cancer Research Program (BCRP), which was established in FY92 to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY05 totaled $1.83 billion. During this time, 23 HBCU/MI Partnership Training Award proposals were received and 9 were recommended for funding. The FY06 appropriation is $127.5 million (M).

B. Program Objectives: The overall goal of the FY06 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 that have the potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations and alliances. Underinvestigated avenues of research and novel applications of existing technologies are strongly encouraged. The BCRP encourages risk-taking research; however, all projects must demonstrate solid scientific judgment and rationale.

The BCRP's objective within this context 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 HBCU/MI Partnership Training Award is intended to enable two or more HBCU/MI faculty-level investigators to obtain the training and experience necessary to obtain independent breast cancer research funding and to support the establishment of an ongoing breast cancer research training program at the applicant HBCU/MI. This award provides mentorship and training at an institutional level by supporting a collaboration between multiple investigators (the Principal Investigator [PI] and Co- Principal Investigator[s] [co-PI(s)]) at the applicant HBCU/MI and at least one ***established breast cancer researcher*** (primary collaborating mentor) at another research institution.

It is expected that through this award

- All investigators (PI, co-PI[s], and collaborating mentors) will work together to complete a coordinated, substantive research project that is likely to result in publication(s) and will have a significant impact on the eradication of breast cancer;
- The quality of the training will enable the HBCU/MI investigators to obtain independent breast cancer research funding;
- A lasting collaboration between the applicant HBCU/MI and mentoring institution will be established; and
- The research collaboration will facilitate the development of an ongoing breast cancer training program at the applicant HBCU/MI by improving research resources at the applicant HBCU/MI.

The focus of these proposals should be on (1) extending and enhancing the HBCU/MI faculty-level investigators' (PI and co-PI[s]) skills so that they may become competitive breast cancer researchers; (2) completing a research project of high relevance to breast cancer that will lead to publication(s); and (3) establishing successful, independently funded breast cancer researchers at the applicant HBCU/MI.

Proposals for the HBCU/MI Partnership Awards may target ***any*** aspect of breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment; however, proposals are especially encouraged in the following research areas:

- Morbidity and/or mortality disparities in underserved/minority populations;
- Epidemiology, including molecular, nutrition, diet, and environment;
- Access to care;
- Treatment and outcomes;

- Social/behavioral sciences; and/or
- Public health or other population-based research.

Please note that only one investigator from the applicant HBCU/MI may be named PI for the proposal in the CDMRP eReceipt Online Proposal Submission System; the additional faculty-level investigators from the applicant HBCU/MI should be identified as the co-PI(s). The key collaborating investigator from the mentoring institution should be identified as the primary collaborating mentor; additional mentors from the collaborating institution should be identified as collaborating mentor(s). ***Proposals will not be evaluated and awards will not be made for "to be named" participants (PI, co-PI[s], or collaborating mentors).***

III. AWARD INFORMATION

Funding for the HBCU/MI Partnership Training Award can be requested for up to $250,000 per year for direct costs. The performance period may be requested for up to 4 years. The maximum funding for a 4-year performance period is $1M in direct costs. In addition, indirect costs should be added as appropriate. The mentoring institution may receive up to 40% of the direct costs during the first year of an award. However, no more than 25% of total direct costs for the full award can be granted to the mentoring institution during the lifetime of the award.

Direct costs for HBCU/MI Partnership Training Awards can cover salary support; tuition for special training and/or other educational opportunities; consultation with established investigators; consultation with scientific and/or technical experts (e.g., statisticians, editors); administrative and technical assistance; purchase or rental of essential equipment; and research supplies, office supplies, and travel. Funds also may be used to establish formal technical assistance programs in which experienced and well-funded investigators provide consultation and mentoring to the applicant institution in grant proposal writing and grantsmanship. The nature of the BCRP does not allow for renewal or supplementation of grants.

This award is designed to train two or more HBCU/MI faculty-level investigators. However, only one investigator from the applicant HBCU/MI may be named PI for the proposal in the eReceipt Online Proposal Submission System; the additional faculty-level investigators from the HBCU/MI should be identified as the co-PI(s). The key collaborating investigator from the mentoring institution should be identified as the primary collaborating mentor; any additional mentors from the collaborating institution should be identified as collaborating mentor(s). ***Proposals will not be evaluated and awards will not be made for "to be named" participants (PI, co-PI[s], or collaborating mentors).***

The CDMRP expects to allot approximately $4M of the $127.5M FY06 BCRP appropriation to fund approximately three HBCU/MI Partnership Training Awards, depending on the quality and number of proposals received.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be HBCU/MI faculty members with doctoral degrees. ***The collaborating mentors are expected to have established breast cancer research programs at the mentoring institution.***

Within these parameters, 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 in Subsection IV.B, "Institutions" below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations (DODGAR) 25.110.)

B. Institutions: Eligible institutions ***are those approved as HBCU/MI*** by the Department of Education. Proposals are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date the program announcement is released. A list of eligible HBCU/MI is available on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions."

Local and state Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. These agencies are expected to explain how their proposals do not overlap with their intramural programs.

C. Duplicate Submissions: Submission of the same research project to the FY06 BCRP to different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

V. PREPROPOSAL PREPARATION AND SUBMISSION INFORMATION

Investigators interested in applying for the BCRP HBCU/MI Partnership Training Award must submit a preproposal. Preproposals will be screened by the Integration Panel to determine those projects that best fulfill the intent of the award mechanism. Invitations to prepare a full HBCU/MI Partnership Training Award proposal will be sent to those investigators selected by the Integration Panel no later than May 2006. ***Do not submit a full HBCU/MI Partnership Training Award proposal unless you receive a letter of invitation.***

A. Preproposal Components Summary: This subsection is a summary of preproposal submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. Prepoposals will be screened using the criteria described in Subsection V.K and Subsection V.M.

1. Applicant Responsibility: The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	None. Not required.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	List the primary investigator from the HBCU/MI as the PI. List the primary collaborating mentor as the "Alternate Submitter." The Proposal Contacts must include the e-mail address of the PI and the primary collaborating mentor. The primary collaborating mentor is responsible for uploading the Letter of Collaboration.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	List the HBCU/MI faculty investigator(s) as "Co-Principal Investigator(s)." List the investigator(s) from the mentoring institution as "mentor(s)." Enter information about additional collaborators and others outside the scope of the proposal who may have a COI in the review of this preproposal.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/ SOW	Typed or Cut and Paste	None. Not required.
Preproposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	None. Not required.
Regulatory Documents	Required Files	PDF	None. Not required.

2. Primary Collaborating Mentor's Responsibility: The primary collaborating mentor (identified as the Alternate Submitter under the Proposal Contacts tab in the CDMRP eReceipt system) is responsible for entering and/or uploading the following information into the CDMRP eReceipt system at https://cdmrp.org:

Item	Tab	Format	Action
Letter of Collaboration	Required Files	PDF	Upload as a PDF file.

3. Contract Representative Responsibility: The HBCU/MI Partnership Training Award preproposal does not require Contract Representative approval before submission.

B. Proposal Format: Preproposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare preproposals for PDF submission.

The main body of the preproposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (approximately 19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Preproposals 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 MB. Some reviewers work from black and white printed copies; therefore, applicants may wish to include text in the preproposal directing the reviewer to the electronic file for parts of the preproposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the preproposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the preproposal are allowed.
- **Language:** English.

Please note that headers should not be included, as the preproposal log number will be electronically captured on each page of the preproposal after receipt.

C. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all preproposals in an organized and easy-to-follow manner. Reviewers expect to see a consistent, prescribed format for each preproposal. ***Failure to adhere to format requirements makes preproposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in preproposal rejection.***

The following will result in administrative rejection of the entire preproposal prior to screening:

- Preproposal body exceeds page limit.
- Preproposal body is missing.
- The PI, co-PI(s) or mentor(s) do not meet eligibility criteria (as described in Subsection IV.A).
- Letter of collaboration is missing.
- Preproposal is incomplete after the deadline.

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

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for screening.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission system is the official preproposal submission file. After conversion of word processing documents to PDF files and before electronic submission, applicants should review their files to ensure that the preproposal complies with the preparation guidelines outlined in this program announcement.

D. Letter of Intent: A Letter of Intent is not required for this award mechanism.

E. Proposal Information: Applicants must submit the Proposal Information as described in https://cdmrp.org before uploading the preproposal and supporting documentation.

- A ***Title/Referral Page*** for the preproposal will be generated from the information uploaded in eReceipt and appended to the preproposal electronically by the CDMRP eReceipt Online Proposal Submission System.

F. Proposal Contacts: The HBCU/MI Partnership Training Award preproposal does not require Contract Representative approval before submission. Therefore, the Contract Representative's contact information is not required for preproposal submission. List the primary investigator from the applicant HBCU/MI as the PI and the primary collaborating mentor as the "Alternate Submitter." The Proposal Contacts must include the e-mail address of

the PI and the primary collaborating mentor. The primary collaborating mentor is responsible for uploading the Letter of Collaboration.

G. Collaborators and Conflicts of Interest (COI): To avoid COI during the screening process, list the names of all scientific participants in the preproposal including collaborators, consultants, and subawardees. As noted above, only ***one*** HBCU/MI investigator may be listed as the PI. All additional faculty-level investigators from the applicant HBCU/MI should be identified as co-PI(s). The investigator(s) from the mentoring institution should be identified as mentor(s). Proposals will not be evaluated and awards will not be made for "to be named" participants (PI, co-PI(s), or mentors).

In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this preproposal.

H. Proposal Abstracts: Abstracts are not required at the time of preproposal submission. The data fields must be completed by typing "N/A" into both the technical abstract and the public abstract data fields.

I. Impact Statement: An Impact Statement is not required at the time of preproposal submission. However, the data field must be completed by typing "N/A" into the Impact Statement data field.

J. Statement of Work (SOW): An SOW is not required at the time of preproposal submission. The data field must be completed by typing "N/A" into the SOW data field.

K. Preproposal Main Body: Start section on a new page; five-page limit inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preproposal.

The preproposal main body is uploaded as a PDF file under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission System.

The investigator is responsible for articulating clearly how the proposed partnership addresses each of the following screening criteria for preproposals:

1. **Training Plan**

    - Explain how this award will train two or more investigators at the applicant HBCU/MI in breast cancer research.
    - Describe how this award will provide investigators at the applicant HBCU/MI with the opportunity to acquire the knowledge and research experience needed to obtain independent breast cancer research funding and to develop a successful, independently-funded training program in breast cancer research at the applicant HBCU/MI.

2. Collaboration: Describe a clear, productive, and substantive collaboration throughout the term of the award between two or more investigators at the applicant HBCU/MI and at least one ***established*** investigator(s) with a strong track record of obtaining funding in breast cancer research at the mentoring institution.

3. Research Project: Describe plans for developing and completing a coordinated, substantive research project that addresses a critical problem in breast cancer research or patient care. The research project may address any aspect of breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment. Topics of particular interest include:

- Disparities in morbidity and/or mortality in underserved/minority populations;
- Epidemiology including molecular, nutrition, diet, and environment;
- Access to care;
- Treatment and outcomes;
- Social/behavioral sciences; and
- Public health and/or other population-based research.

4. Research Resources: Describe how the research resources at the applicant HBCU/MI will be improved through this award.

L. Preproposal Supporting Documentation: Submit only material specifically requested or required in this program announcement. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the preproposal.*** Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the preproposal.

Supporting Documentation must be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission System. All documents that require signatures must be signed and incorporated into the supporting documentation file before it is submitted.

The items to be included in the Supporting Documentation are:

1. 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).

2. Biographical Sketches: Four-page limit per individual. Include biographical sketches for all key personnel including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in a lower preproposal ranking. 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.

M. Letter of Collaboration. Start section on a new page; two-page limit. The Letter of Collaboration must be uploaded by the primary collaborating mentor (Alternate Submitter).

The primary collaborating mentor must describe the research collaboration using the following outline:

- **Collaboration:** Describe how formal training, informal and formal communication, and access to facilities and equipment will be provided for this mentored research experience. Address institutional support for each collaborating mentor's time and for access to research resources for the HBCU/MI investigators (PI and co-PI[s]).
- **Mentoring:** Demonstrate that each collaborating mentor is experienced in breast cancer research, including previous success in obtaining funding for breast cancer research. Describe each collaborating mentor(s)'s experience in mentoring scientists. Indicate the time commitment of the collaborating mentor(s) to the collaboration.
- **HBCU/MI Investigators:** Provide details on the qualifications of each HBCU/MI investigator (PI and co-PI[s]). Demonstrate how this collaboration will advance the capabilities of the PI and co-PI(s) to develop and sustain an independent research program in breast cancer at the HBCU/MI.

N. Submission Date and Time: Preproposals must be uploaded on the CDMRP eReceipt Online Proposal Submission System by the deadline. Preproposals that are incomplete will ***not*** be considered for review. The CDMRP eReceipt Online Proposal Submission System will not accept data entry or file uploads after the ***5:00 p.m. Eastern time, March 28, 2006*** deadline.

VI. 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. Proposals will be evaluated according to peer and programmatic review criteria in Section VII.

1. Applicant Responsibility: The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	None. Not required.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.

Item	Tab	Format	Action
Proposal Contacts	Proposal Contacts	Typed	List the primary investigator from the HBCU/MI as the PI. List the primary collaborating mentor as the "Alternate Submitter." Enter contact information for the PI, Alternate Submitter, and the Contract Representative at the applicant's institution.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	List the HBCU/MI faculty investigator(s) as "Co- Principal Investigator(s)." List the investigator(s) from the mentoring institution as "mentor(s)." Enter information about collaborators and others outside the scope of the proposal who may have a COI in the review of this proposal.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/ SOW	Typed or Cut and Paste	Enter the Technical Abstract, Public Abstract, Impact Statement, and SOW in separate data fields.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	Upload as a PDF file.
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

2. Contract Representative Responsibility: The Contract Representative (CR) or institutional official responsible for sponsored program administration (or equivalent) at the applicant's institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative's Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.

Item	Tab	Format	Action
USAMRAA[a]-Required Documents	My Profile for the CR	PDF	Upload Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Collaborators and COI, Abstracts/Impact Statement/SOW, and Required Files ***before*** the submission deadline of 5:00 p.m. Eastern time, June 27, 2006.

[a]US Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of the proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27cm) in all directions.
- **Print Area:** 7.5 x 10.0 inches (approximately 19.05 cm x 25.40 cm).
- **Color, High-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 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. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.

- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are allowed.
- **Language:** English.

Please note that headers should not be included, as the proposal log number will be captured electronically on each page of the proposal after receipt.

C. 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. ***Failure to adhere 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.***

The following will result in administrative rejection of the entire proposal before it reaches peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- PI, co-PI(s), or mentor(s) do not meet eligibility criteria.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.

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.

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

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and prior to electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

D. Letter of Intent (LOI): A Letter of Intent is not required for this award mechanism.

E. Proposal Information: Applicants are required to submit the Proposal Information as described in https://cdmrp.org before uploading the proposal, supporting documentation, and budget information.

- A ***Title/Referral Page*** for the proposal will be generated from the information uploaded in eReceipt and electronically appended to the proposal by the CDMRP eReceipt system.

F. Proposal Contacts: List the primary investigator from the HBCU/MI as the PI and the primary collaborating mentor as the "Alternate Submitter." The Proposal Contacts ***must*** include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant's institution. The Proposal Contacts must be approved by the Contract Representative at the applicant's institution.

G. Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposal including collaborators, consultants, and subawardees. Only ***one*** HBCU/MI investigator may be listed as the PI. All additional faculty-level investigators from the HBCU/MI should be identified as co-PI(s). The collaborating investigator(s) from the mentoring institution should be identified as mentor(s). Proposals will not be evaluated and awards will not be made for "to be named" participants (PI, co-PI(s), or mentors).

In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this proposal.

H. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Each abstract must include the applicant's name and the title of the proposal. A structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important in both the peer review and programmatic review processes. 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 of paramount importance that the applicant submits abstracts that describe the proposed work fully. Each abstract must be entered into the appropriate data field under the "Abstract/Impact/SOW" tab of the CDMRP eReceipt system.

Applicants can type the abstracts or "cut and paste" them from a word processing application into the respective data fields. ***Spell out all Greek letters, other non-English letters, and symbols.***

Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included in either the technical or the public abstract.

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract must provide a clear and concise overview of the proposed work. Use the outline below when preparing the structured technical abstract.

- **Training Plan**
  - Describe how the training plan will provide HBCU/MI faculty investigators with the opportunity to obtain independent breast cancer research funding and support the establishment of an independently funded breast cancer research training program at the applicant HBCU/MI.

- Describe how the research resources at the applicant HBCU/MI will be improved through this award.

- **Research Plan**
  - Background: Present 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.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Impact: Provide a brief statement explaining the impact of the proposed work to the program goals. Describe how the proposed project will have an impact on breast cancer research or patient care.

2. Public Abstract: Sample public abstracts can be found at .https://cdmrp.org/samples.cfm The public abstract is intended to communicate the purpose and rationale of the study to a non-scientifically trained audience. 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.

- Describe the objective and rationale for the proposal in a manner readily understood by non-scientists.
  - Describe how the training plan will provide HBCU/MI faculty investigators with the opportunity to obtain independent breast cancer research funding and support the establishment of an independently-funded breast cancer research training program at the HBCU/MI.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research.
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a consumer-related outcome?
- If the research is too basic for clinical applicability, describe 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?

I. Impact Statement – 5,700-character limit, including spaces (approximately one page): The Impact Statement is captured in a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt system. Applicants can type the Impact Statement into the data field or "cut and paste" it from a word processing application.

State explicitly how the proposed work will provide the HBCU/MI faculty investigators with the training needed to obtain independent breast cancer research funding and support establishment

of an independently funded breast cancer research training program at the applicant HBCU/MI. Describe how the proposed work will have an impact on breast cancer research or patient care. Describe how the expected results of the proposal will contribute to the goals of eradicating breast cancer and advancing research in the field. Clearly and simply state how the research will significantly advance methods, concepts, prevention, diagnosis, or treatment of breast cancer or quality of life for patients. The Impact Statement will be available at both peer and programmatic reviews.

J. Statement of Work – 11,400-character limit, including spaces (approximately two pages): The SOW is captured as a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt Online Proposal Submission System. Applicants can type in the SOW into the data field or "cut and paste" it from a word processing application.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include DOD-funded tasks only. Sample SOWs can be found at https://cdmrp.org/samples.cfm.

The SOW should:

- Describe the training plan to be accomplished as tasks (tasks may relate to specific aims);
- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the performance period of the proposed effort;
    - Allow 4 to 6 months for regulatory review and approval processes for human use studies;
    - Allow 2 months for regulatory review and approval processes for animal studies;
- For animal and human studies (including tissue, anatomical, or biological substances) indicate the sample size projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each stage of the project.

K. Proposal Main Body: Start section on a new page; 10-page limit inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the proposal.

The proposal main body is uploaded as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

Using the Award Mechanism Description in Subsection II.C as guidance, describe the proposed HBCU/MI Partnership using the following outline:

1. Background: Provide a brief statement of the ideas and reasoning on which the proposed collaboration(s) is based. State the specific aims of the study (or studies) and how these will help to develop competitive, successful, independently funded breast cancer researchers at the applicant HBCU/MI. Briefly describe the methods to be used. Cite relevant literature references.

2. Collaborative Arrangement: Concisely describe the proposed interaction between the applicant HBCU/MI and mentoring institution. Provide information on the PI and co-PI(s) from the applicant HBCU/MI who will be trained through this award. Provide details on the qualifications and attributes of the PI and co-PI(s), and demonstrate their commitment to developing and sustaining a breast cancer research program at the applicant institution. Demonstrate the applicant HBCU/MI's commitment to developing and sustaining the collaboration. Explain the pertinent qualifications of the collaborating mentor(s) including their record in acquiring funding for breast cancer research and experience in training breast cancer researchers. List the facilities at the mentoring institution that will be made available to the PI and co-PI(s) through this collaboration. Include any information on previous training/collaborations between the mentoring institution and the applicant HBCU/MI, if applicable.

3. Training Program: Present a clearly articulated plan for developing a training program at the applicant HBCU/MI that focuses on the biology, etiology, prevention, detection, diagnosis, and/or treatment of breast cancer. Discuss the proposed training program in depth, including any planned special seminar series, journal clubs, expert consultations, and technical and assistance programs. Describe the collaborating mentor(s) qualifications and role in managing the training program. Specify how the collaboration will result in training needed to produce competitive, successful, independently funded breast cancer researchers at the applicant HBCU/MI and development of an ongoing, independently funded breast cancer research training program at the applicant HBCU/MI.

4. Research Project: Describe the ideas and reasoning behind the proposed research project. Include a summary of the research strategy, experimental design, and methodology. Describe how the proposed research will provide the HBCU/MI faculty investigators with the knowledge and experience needed to obtain independent breast cancer research funding and develop an ongoing, independently funded breast cancer research training program at the applicant HBCU/MI.

5. Research Resources: Describe the facilities available at the applicant HBCU/MI and how research resources at the applicant institution will be improved through this award. Explain how the research resources will advance the HBCU/MI toward establishing ongoing, independently funded breast cancer researchers and an independent breast cancer research training program.

6. Communication: Outline the communication plan that will be used to establish and maintain the proposed collaboration. This plan should include frequent and ongoing virtual and real-time interactions; a 1-week visit or the time required to learn one technique will not be considered sufficient. Discuss the frequency of communication and face-to-face meetings

between and among the PI, co-PI(s), and collaborating mentor(s). If the PI, co-PI(s) and the collaborating mentor(s) are geographically far apart, explain in detail how communication and training will be accomplished. Provide a plan for jointly preparing reports that offer updates on the status of the training and collaboration by the PI, co-PI(s), and collaborating mentor(s). These reports should show how each institution is responding to issues or problems that may arise. These status reports may not be used in lieu of actual meetings between the collaborators.

L. Supporting Documentation: Submit only material specifically requested in this program announcement. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.*** Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal.

Supporting Documentation must be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. All documents that require signatures must be signed and incorporated into the supporting documentation file before it is submitted.

The first item in the Supporting Documentation file is the ***Checklist/Table of Contents page***. The requested, allowable items in this section must be listed in the Checklist/Table of Contents; these include:

1. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used in the main body of the proposal.

2. 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).

3. Biographical Sketches: Four-page limit per individual. Include biographical sketches for all key personnel, including HBCU/MI investigators (PI and co-PI[s]), collaborating mentors, and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower proposal 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.

4. Existing/Pending Support: Start section on a new page; no page limit. List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel (PI, co-PI(s), and collaborating mentor[s]) on a separate page. If no support exists, state "None." Proposals submitted under this program announcement should not duplicate other funded research projects.

5. Facilities/Equipment Description: No page limit. Describe the facilities available at both the applicant HBCU/MI and mentoring institution for performing 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 whether Government-owned facilities or equipment are proposed for use.

6. Letters of Support: Provide signed letters of support from collaborating mentor(s) or institutions (applicant and collaborating) including:

a. ***A letter signed by the department chair, dean, or equivalent official from the applicant HBCU/MI institution*** documenting the institution's commitment to the proposed training program. This letter should reflect the extent to which the institution will support the collaboration by relieving participants (PI and co-PI[s]) of their academic and/or clinical responsibilities so that they will have sufficient time for collaboration and training, provide access to appropriate facilities, and provide opportunities for professional interactions with senior colleagues.

b. ***A letter signed by the department chair, dean, or equivalent official at the mentoring institution*** describing the institution's commitment to the training/development/mentorship of the PI and co-PI(s) from the applicant HBCU/MI institution and the nature of the proposed collaboration/training.

c. Letters of support from any additional consultants/collaborators who will be supplying essential assistance to the proposed project. These letters must describe the roles of these individuals in the research/training.

7. Letter of Collaboration: Four-page limit. The primary collaborating mentor must describe the research collaboration using the following outline:

a. Collaboration: Address the collaboration that will be established, demonstrating how the mentoring institution and each collaborating mentor will support the mentored research experience. Detail the communication plan, including the schedule of face-to-face meetings and opportunities for informal communication. Provide plans for formal training of the PI and co-PI(s) from the applicant HBCU/MI where applicable. Provide clear evidence of institutional support for each collaborating mentor's time and access of the PI and co-PI(s) from the HBCU/MI to the mentoring institution's facilities and equipment.

b. Mentoring: Demonstrate that each collaborating mentor has experience in breast cancer research and has success in acquiring funding in breast cancer research. Provide evidence of each collaborating mentor's experience as a scientific mentor. Indicate the time commitment to the collaboration.

c. Personnel: Provide an assessment of the background and preparation of the PI and co-PI(s). Demonstrate how this collaboration will foster the professional development of

the PI and co-PI(s) and advance the development of a successful, independently funded breast cancer research program at the applicant HBCU/MI.

8. 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 publications are included in the submission, the extra items will not be peer reviewed.

M. Budget Information: Applicants must complete the Detailed Cost Estimate form and the Budget Justification form, and upload them as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. When a proposal requesting funding as part of a larger study is submitted, the proposal's budget justification should include only DOD-funded tasks.

1. Funding Restrictions: Funding for the HBCU/MI Partnership Training Award can be requested for up to $250,000 per year for direct costs. The performance period may be requested for up to 4 years. The maximum funding for a 4-year performance period is $1M in direct costs. In addition, indirect costs should be added as appropriate. The mentoring institution may receive up to 40% of the direct costs during the first year of an award. However, no more than 25% of total direct costs for the full award can be granted to the mentoring institution during the lifetime of the award.

Direct costs for HBCU/MI Partnership Training Awards can cover salary support; tuition for special training and/or other educational opportunities; consultation with established investigators; consultation with scientific and/or technical experts (e.g., statisticians, editors); administrative and technical assistance; purchase or rental of essential equipment; and research supplies, office supplies, and travel. Funds also may be used to establish formal technical assistance programs in which experienced and well-funded investigators provide consultation and mentoring to the applicant institution in grant proposal writing and grantsmanship. The nature of the BCRP does not allow for renewal or supplementation of grants.

The travel allotment is $1,800 per year per investigator for up to five investigators from the HBCU/MI to attend scientific/technical meetings. An additional $1,800 per investigator should be requested for up to five investigators from the HBCU/MI and three investigators from the mentoring institution to attend two, 3½-day Breast Cancer Era of Hope meetings which are held biennially to disseminate the results of the DOD-sponsored research. It is anticipated that the next Era of Hope Meeting will be held in October 2007. The costs of travel between collaborating institutions have no set limit.

2. Detailed Cost Estimate Form and Budget Justification Instructions: Budget is an important consideration in both peer review 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.*** All costs must be entered in U.S. dollars.

The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property and equipment, and/or supplies (e.g., drugs, devices, reagents) directly benefiting and specifically identifiable to the research project. ***It is expected that institutions will share the cost of equipment purchased for this research proposal. Please see full details under "Major Equipment" in Subsection VI.M.2.c.***

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).

Follow the instructions below when providing the information requested in the Detailed Cost Estimate form.

a. Personnel

i. Name: Beginning with the applicant (PI), list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all co-PI(s), collaborating mentor(s), collaborating investigators, research associates, individuals in training, and support staff.

Only one investigator from the applicant HBCU/MI may be identified as the Principal Investigator (PI) for the proposal; the additional faculty-level investigators from the HBCU/MI should be identified as the co-Principal Investigator(s) (co-PI[s]). The key collaborating investigator from the mentoring institution should be identified as the primary collaborating mentor (Alternate Submitter); any additional mentors from the collaborating institution should be identified as the collaborating mentor(s).

ii. Role on Project: Identify the role of each participant listed. 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 Government 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 applicant's qualifications and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting proposals for funding. List the percentage of each appointment to be spent on this project for each key staff member. Include the percent effort of all unpaid collaborators and consultants.

Clinical studies must have a clinical coordinator who has sufficient time dedicated to the project to carry out the record keeping, coordination, and/or other administrative duties the project entails.

vi. Salaries Requested: Enter the salaries in whole U.S. dollars for each position for which funds are requested. Calculate the salary request by multiplying an individual's institutional base salary by the percentage of effort on the project.

vii. Fringe Benefits: Fringe benefits for each position may be requested in accordance with institutional guidelines, provided the costs for all sponsors are treated consistently by the applicant's organization. Provide documentation to support the fringe benefits.

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

b. Consultant Costs: Provide the names and organizational affiliations of all consultants whether or not funds are requested.

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. However, the greater need for equipment support at an HBCU/MI is recognized by the DOD BCRP and will be taken into consideration. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.

i. If the purchase of equipment for this research project is requested, it is expected that institutions will share 50% of the cost.

ii. Permanent equipment is any article of nonexpendable tangible property having a useful life of 2 years or longer and an acquisition cost of $5,000 or more per unit.

iii. The basis for the cost of each item of permanent equipment included in the budget must be disclosed.

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

d. Materials, Supplies, and Consumables: A general description and estimated total 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 will be purchased, state the species, strain (if applicable), and the number of animals to be used. If human cell lines are to be purchased, state the source and the description.

e. Travel Costs: Costs for travel to scientific/technical meetings may not exceed $1,800 per year per investigator for up to five investigators from the HBCU/MI to attend scientific/technical meetings. An additional $1,800 per investigator should be requested for up to five investigators from the HBCU/MI and up to three investigators from the mentoring institution to attend two 3½-day Breast Cancer Era of Hope meetings which are held biennially to disseminate the results of the DOD-sponsored research. It is anticipated that the next Era of Hope Meeting will be held in October 2007.

Travel costs associated with the execution of the proposed work should be entered in this section. If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity (USAMRAA).

f. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses associated specifically with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs 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 to be awarded by subcontract or subgrant is required. For awards totaling $10,000 or more:

- Identify the type of award to be used (e.g., cost reimbursement, fixed price);
- Identify the proposed subcontractor or subgrantee, if known, and provide an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Specify whether the award will be competitive and, if noncompetitive, provide a rationale to justify the absence of competition; and
- Provide 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 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 in 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. Directs costs, indirect costs, and the total cost for the entire proposed period of support should equal the amount entered in the "Required Files" tab at https://cdmrp.org.

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

N. 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 (see Subsection VIII.D.5, Research Involving Human Subjects and/or Biological Substances/Cadavers; and Subsection VIII.D.4, Research Involving Animals) with the proposal. The applicant should provide these documents to the USAMRMC only upon request.

O. USAMRAA-Required Documents: The Contract Representative at the applicant's institution must upload the current version of the institution's negotiated Rate Agreement, the Certifications and Assurances for Assistance Agreements, and the Representations for Assistance Agreements. These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system by the proposal submission deadline.

P. Submission Date and Time: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution by the deadline. Proposals that are incomplete or not approved electronically before the deadline will not be considered for review. The CDMRP eReceipt system will ***not*** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, June 27, 2006 deadline.

The timeline for the HBCU/MI Partnership Training Award is:

Preproposal Submission Deadline:	***5:00 p.m. Eastern time, March 28, 2006***
Preproposal Screening (First Tier):	Mid-April 2006
Full Proposal Invitations:	April 2006
Online Proposal Information:	Required prior to proposal submission
Proposal Submission/Approval Deadline:	***5:00 p.m. Eastern time, June 27, 2006***
Peer Review (Second Tier):	August 2006
Programmatic Review (Third Tier):	November 2006
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after the completion of programmatic review
Award Start Date:	Anticipated between December 2006 and September 2007

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

Several steps are critical to successful proposal submission:

- The Proposal Information must be "Finalized for CR Approval" before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.
- Proposal Contacts must be "Finalized for CR Approval" before the proposal is submitted. The e-mail address of a Contract Representative at the applicant's institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.
- The Contract Representative authorized to negotiate on behalf of the applicant's 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, June 27, 2006 deadline.
- Some items in the proposal including figures, tables, graphs, letters, or publications will need to be scanned electronically. These documents should be scanned at a resolution of 300 dpi or less.

- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g., Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Detailed Cost Estimate form and the Budget Justification form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VII. PREPROPOSAL AND PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview: HBCU/MI Partnership Training Award proposals are evaluated using a three-tier review process. The first tier is the review of preproposals. The second tier is a scientific peer review of invited proposals against established criteria for determining scientific merit. The third tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program.

1. Preproposal Review: The HBCU/MI Partnership Training Award preproposals are screened by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. The primary responsibility of the Integration Panel during preproposal screening is to select applications to be invited to submit full HBCU/MI Partnership Training Award proposals.

2. Peer Review: Peer review is conducted by scientific and consumer reviewers. The primary responsibility of the peer reviewers 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.

Scientific reviewers are selected for their subject matter expertise and 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 process by bringing the patient perspective to the assessment of science and the relevance of the research.

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: Programmatic review is conducted by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer

members represent national advocacy constituencies. A function of programmatic review is to structure 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. Integration Panel members base programmatic review primarily on the peer review summary statements and the proposal abstracts. The Integration Panel also may review SOWs and impact statements. Full proposals are not forwarded to programmatic review.

B. Review Criteria

1. Preproposal Review: HBCU/MI Partnership Training Award preproposals and letters of collaboration will be screened according to the criteria listed in Subsection V.K and Subsection V.M to determine those projects that best fulfill the intent of the award mechanism. Following completion of the preproposal screening process, invitations to prepare a full HBCU/MI Partnership Training Award proposal will be sent to selected applicants.

Do not submit a full HBCU/MI Partnership Training Award proposal unless you receive a letter of invitation.

2. Peer Review: HBCU/MI Partnership Training Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

- **Training Plan**
  - How the proposed training will develop breast cancer researchers at the applicant HBCU/MI by the end of the award period.
  - How the award will support the development of an independent training program in breast cancer research at the applicant HBCU/MI.
  - How the applicant HBCU/MI and mentoring institution plan to sustain the interactive environment necessary to develop and maintain an ongoing, effective training program.
- **HBCU/MI Institution**
  - Whether the PI and co-PI(s) meet the eligibility criteria.
  - Whether the PI, the co-PI(s), and the applicant HBCU/MI demonstrate a commitment to developing an ongoing program focused on breast cancer research.
  - Whether the applicant HBCU/MI demonstrates a commitment to establishing and sustaining the collaboration.
  - Appropriateness of the PI's and each co-PI's background, experience, and expertise to accomplish the proposed work.
  - How the research resources at the applicant HBCU/MI will be improved through the proposed training and research.

- **Mentoring Institution**
  - Whether each collaborating mentor has demonstrated that he or she is an established breast cancer researcher.
  - How each collaborating mentor's qualifications, experience, and record in breast cancer research supports the development of a productive collaboration with the applicant institution.
  - Whether the mentoring institution demonstrates a commitment to the development of an ongoing breast cancer research program at the applicant HBCU/MI.
  - Whether the collaborating mentor(s) and mentoring institution have a strong record of developing training programs and acquiring funding for breast cancer research.
- **Collaboration**
  - How the plan for communication will aid in the establishment and/or maintenance of an ongoing collaboration between the participating institutions.
  - Whether the proposed collaboration will be sustained beyond the conclusion of this award.
- **Research**
  - Whether the PI, co-PI(s), and collaborating mentor(s) will contribute equally to the planned project.
  - Whether the research is of sufficient depth and duration to lead to publication of results in the peer-reviewed literature.
  - How the proposed research will provide the HBCU/MI investigators with the knowledge and experience needed to independently obtain breast cancer research funding and establish a competitive, independently funded breast cancer research training program at the applicant HBCU/MI.
- **Resources/Environment**
  - Whether the applicant HBCU/MI has the appropriate scientific environment, resources, and collaborative arrangements needed to develop and sustain a breast cancer research program.
  - The appropriateness of the scientific environment for the proposed research at both the applicant HBCU/MI and mentoring institution.
  - The quality and extent of institutional support, including whether both institutions demonstrate a strong institutional commitment to supporting the development of the breast cancer research program by relieving participants of some of their academic or clinical responsibilities so that they will have sufficient time for the collaboration and training.
  - Whether the appropriate management and leadership for the proposed partnership are present at the applicant HBCU/MI and the mentoring institution.

- **Impact**
  - To what extent the proposed research collaboration and training program addresses a critical problem in breast cancer research or patient care.
  - How the research makes an original and important contribution to the goal of advancing research on the prevention, detection, or treatment of breast cancer.
  - The difference this proposal will make on breast cancer research or patient care, if successful.
- **Budget**
  - How the budget is appropriate for the work proposed.
  - Whether the applicant HBCU/MI will receive at least 75% of the direct costs over the lifetime of the award to use on projects directly related to building a breast cancer research program.
  - Whether the mentoring institution will receive no more than 40% of direct costs budgeted for the first year of the award and no more than 25% of the direct costs budgeted over the life of the award.

3. Programmatic Review: Criteria used by the Integration Panel to make funding recommendations that maintain the BCRP's broad portfolio include:

- Ratings and evaluations of the peer reviewers (scientific and consumer),
- Programmatic relevance,
- Relative innovation and impact,
- 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 Integration Panel and recommended for funding to the Commanding General, USAMRMC.

VIII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: Each applicant will receive notification of the award status of his or her proposal. A copy of the peer review summary statement will be posted to the CDMRP eReceipt system. Applicants can expect to receive notification approximately four weeks after programmatic review.

B. Administrative Requirements: Awards are made to organizations, not individuals. An applicant must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, 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) to be eligible for an award. ***Any organization requesting receipt of an award through 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***.

Transferring a HBCU/MI Partnership Training Award will not be permitted.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the applicant's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

For multi-institutional studies, collaborating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation to ensure the successful establishment and maintenance of the research project. An intellectual and material property plan agreed to by all participating institutions may be required during award negotiations.

The award start date will be determined during the negotiation process.

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiation, 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 DOD 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 the 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 required; it will be requested at a later date. A Facility Safety Plan from the applicant's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp. If the applicant's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan.

Specific requirements for the Facility Safety Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

If multiple research sites/institutions are funded in the proposal, 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: Specific documents relating to the use of animals in the proposed research will be requested by the CDMRP if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of USAMRMC Office of Research Protections (formerly Regulatory Compliance and Quality), must review and approve all animal use prior to the start of working with animals. Applicants must complete and submit the animal use appendix titled "Research Involving Animals," which can be found on the ACURO website https://mrmc-www.army.mil/rodorpaurd.asp).

Questions related to animal use may be directed to ACURO as follows:

Phone:	301-619-6694
Fax:	301-619-4165
E-mail:	acuro@amedd.army.mil
Mail:	MCMR-ZB-PA 504 Scott Street Fort Detrick, MD 21702-5012

Specific requirements for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

5. Research Involving Human Subjects/Biological Substances/Cadavers: In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or human biological substances or cadavers, a second tier of IRB review and approval also is required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Office of Research Protections. 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.

a. Requirements: Specific requirements for research involving human subjects, human biological substances, and/or cadavers can be found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix.pdf.

Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

It is expected that there will be timely resolutions of human subjects protocols submitted to the investigator's local IRB.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.detrick.army.mil/rodorphrpo.asp.

b. Informed Consent Form: An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

c. Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980) applicable to DOD-sponsored research before writing a research protocol. Title 10 United States Code Section 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 before 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.

d. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells: Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45 of the Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g-2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

e. Clinical Trial Registry: All applicants are required to register clinical trials individually on http://www.clinicaltrials.gov/ using a Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: CDMRP-CDMRP Log Number-A, B, C, etc. ***Clinical trials must be registered prior to enrollment of the first patient.*** All trials that meet the definition on the NIH database (see http://prsinfo.clinicaltrials.gov/, click on "Data Element Definitions," see section 6, "Study Phase" and "Study Type") including all Phase I-IV clinical trials, as well as trials that do not fit into one or more phases, but that are clearly interventional or observational (e.g., some epidemiological or behavioral studies)are required register. Address questions on registration to the www.clinicaltrials.gov administrator.

6. Award/Regulatory Approval: 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 once an award is made. The applicable USAMRMC regulatory office will forward written approvals directly to the applicant.

E. Reporting Requirements: The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full USAMRMC reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

Reporting requirements include the following:

1. Research Progress Reports: 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. Copies of all scientific publications and patent applications resulting from CDMRP funding should be included in the progress report.

2. Fiscal Reports: 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.

3. Non-Exempt Human Studies Reports: For non-exempt, human subjects research, documentation of local IRB continuing review (in the intervals specified by the local IRB but at least annually) and approval for continuation must be submitted directly to the Office of Research Protections – Human Research Protection Office.

4. Animal Use Reports: Applicants are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

IX. OTHER INFORMATION

A. Disclosure of Proprietary Information outside the Government: By submitting 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 are not 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. All other sources also should be consulted to the extent practical for the same purpose.

D. Inquiry Review Panel: Applicants may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the 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.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US 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.

X. 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
CFR	Code of Federal Regulations
COI	Conflicts of Interest
CR	Contract Representative
DOD	Department of Defense
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FY	Fiscal Year
hES	Human Embryonic Stem
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
M	Million
MB	Megabytes
MPEG	Moving Picture Experts Group
NIH	National Institutes of Health
OMB	Office of Management and Budget
PDF	Portable Document Format
PI	Principal Investigator
SOW	Statement of Work
SPORE	Specialized Programs of Research Excellence
TIFF	Tagged Image File Format
URL	Uniform Resource Locator
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio