Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

The Fiscal Year 2005 (FY05) Appropriation Bill was signed by President Bush on August 5, 2004. This program announcement is being released prior to the receipt of funds appropriated in the bill for this research program; funding of proposals received in response to this program announcement is contingent on the receipt of funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Collaborative Research Award (CRA).

B. Program Name: Department of Defense (DOD) FY05 Ovarian Cancer Research Program (OCRP).

C. Funding Opportunity Number: OC05-CRA.

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, proposal format, or required documentation may be addressed to the CDMRP at:

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-ZB-C (OC05-CRA) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

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

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

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

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

H. Website Address to Access Application Package: Proposals must be submitted electronically at https://cdmrp.org/proposals. The website contains all the information, forms, documents, and links needed to apply.

I. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the HBCU/MI Collaborative Research Award is to provide research training and experience for HBCU/MI investigators involved in ovarian cancer or related research. A major aim of this award is to provide the opportunity for mentorship by supporting collaborations, specifically those between an HBCU/MI investigator conducting ovarian cancer or related research with little or no research funding and an established investigator in ovarian cancer research for the purpose of developing independent, competitive ovarian cancer researchers at HBCU/MI.

This award is intended to provide support for HBCU/MI faculty researchers with doctoral degrees that have little or no resources. The HBCU/MI Collaborative Research Award will provide an HBCU/MI investigator an opportunity to collaborate with and be mentored by well-established ovarian cancer researcher(s).

The HBCU/MI Collaborative Research Award proposals must address etiology/tumor biology, preclinical development of targeted therapies (excluding clinical trials), or early detection/diagnosis of ovarian cancer. All HBCU/MI Collaborative Research Award proposals must include preliminary data relevant to the proposed project.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately $1.2 million (M) is available to fund FY05 OCRP HBCU/MI Collaborative Research Awards.
- Approximately one HBCU/MI Collaborative Research Award will be funded.
- Funding for the HBCU/MI Collaborative Research Award can be requested for a maximum of $750,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

- This award mechanism must include a Principal Investigator (PI) from an HBCU/MI and an established investigator from a collaborating institution.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be HBCU/MI doctoral-level faculty members. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible HBCU/MI institution.

Applicants may submit only one proposal per award mechanism as the PI to the DOD OCRP.

B. Institutions: Eligible institutions are those approved as HBCU/MI by the Department of Education. See the Full Text of the Program Announcement for the website containing the list of HBCU/MI.

Eligible collaborating institutions include for-profit, non-profit, public, and private organizations.

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

D. Other Eligibility Criteria: Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from HBCU/MI, and administrative compliance issues.

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

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

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

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

C. Pre-Proposal Submission Date and Time: Pre-proposal Deadline: October 26, 2004, 5:00 p.m. Eastern time. Pre-proposals must be submitted through the CDMRP eReceipt system. Pre-proposals will be screened by the OCRP Integration Panel to determine which projects best

fulfill the intent of the award mechanism. Following the pre-proposal screening process, invitations to submit full proposals will be sent to selected applicants. Only those invited may submit full proposals.

D. Invited Proposal Preparation: Following completion of the pre-proposal screening process, invitations to prepare a full HBCU/MI Collaborative Research Award proposal will be sent to selected investigators no later than mid-November 2004. ***Do not submit a full HBCU/MI Collaborative Research Award proposal unless you receive a letter of invitation.***

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

E. Invited Proposal Submission Date and Time: Full Proposal Deadline: February 15, 2005. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. Eastern time.

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

VI. PROPOSAL REVIEW INFORMATION

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

VII. AWARD ADMINISTRATION INFORMATION

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

B. Reporting Requirements: Annual reporting requirements apply.

Full Text of Program Announcement

I. GENERAL INFORMATION

The Fiscal Year 2005 (FY05) Appropriation Bill was signed by President Bush on August 5, 2004. This program announcement is being released prior to the receipt of funds appropriated in the bill for this research program; funding of proposals received in response to this program announcement is contingent on the receipt of funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Collaborative Research Award (CRA).

B. Program Name: Department of Defense (DOD) FY05 Ovarian Cancer Research Program (OCRP).

C. Funding Opportunity Number: OC05-CRA.

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

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-ZB-C (OC05-CRA) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission or the process of electronic submission. The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

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

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

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

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

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

I. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The HBCU/MI Collaborative Research Award is part of the DOD OCRP, which was established in FY97 to promote innovative research directed toward eliminating ovarian cancer. The FY05 appropriation is $10 million (M). Appropriations for the OCRP from FY97 to FY05 total $91.7M. During this time, the OCRP has received 874 proposals and has funded 92 projects. This is the first year in which HBCU/MI Collaborative Research Awards are being offered.

B. Program Objectives: The overall goal of the FY05 OCRP is to promote research directed toward eliminating ovarian cancer by supporting innovative research, attracting independent investigators, and supporting HBCU/MI investigators in developing research resources. Within this context, the key initiative of this announcement is to support a partnership in which an HBCU/MI faculty investigator collaborates with an established ovarian cancer researcher to obtain the knowledge and experience to establish an independent ovarian cancer research program. Complementing current research by other funding agencies, the FY05 OCRP is encouraging scientific inquiry of epithelial ovarian carcinoma, the most common form of ovarian

cancer, and/or primary peritoneal carcinoma, a disease with a clinical course similar to epithelial ovarian carcinoma.

Although the OCRP is interested in many research disciplines and in the past has funded a diverse portfolio of disciplines studying ovarian cancer, recent advances in the understanding of ovarian cancer present unique opportunities that can benefit significantly from directed research efforts. Therefore, the **FY05 OCRP is focusing only on the following three research areas of emphasis. Please note that proposals not addressing at least one of these FY05 research areas of emphasis will be administratively withdrawn and will not be considered for funding.**

Etiology/Tumor Biology

Research in ovarian cancer etiology and tumor biology seeks to better understand the causes or origins of ovarian cancer and to better understand the interactions of ovarian cancer cells with the host micro-environment. Elucidation of the mechanisms of tumor growth, angiogenesis, invasion, progression, and metastasis is needed, especially those aspects unique to ovarian cancer. The limited knowledge of ovarian cancer biology and the process of carcinogenesis are among the greatest barriers to progress in ovarian cancer research. Increased basic research in ovarian cancer etiology and tumor biology is an essential prerequisite for the development of new screening strategies, preventive interventions, and treatments for ovarian cancer. The OCRP encourages proposals aimed at developing and evaluating novel tools, reagents, and methods to visualize specific molecular pathways in vivo (molecular imaging), particularly those pathways that are key targets in ovarian cancer.

Preclinical Development of Targeted Therapeutics (Excluding Clinical Trials)

To encourage the development of new and effective ovarian cancer therapies, the OCRP is interested in receiving proposals that focus on the preclinical development of targeted therapies. Examples include drugs, substances, or agents that can identify and attack specific genes or pathways associated with ovarian cancer cells and ovarian cancer progression. The OCRP encourages proposals focusing on the development and validation in preclinical models of either (1) a therapy targeted to an individual's tumor and the tumor's defect or (2) the combination of specific drugs/agents targeted to multiple locations and/or defects. In addition, the OCRP is interested in projects that use imaging techniques to visualize these processes.

The FY05 OCRP is **not** interested in projects proposing traditional chemotherapy trials and will only fund projects proposing preclinical work within this FY05 research area of emphasis. No clinical trials will be funded.

Early Detection/Diagnosis

The American Cancer Society estimates that 25,590 new cases of ovarian cancer will be diagnosed in 2004, and 16,090 women will die from the disease.[1] Data demonstrate that if diagnosed at an early stage the 5-year survival rate is 95%; however, only 29% of ovarian cancer cases are detected at this stage. The OCRP recognizes the crucial need for improved early detection and improved diagnostics, including screening tools such as specific biochemical markers, targeted antibodies, and novel imaging systems and techniques. The OCRP is

[1] American Cancer Society - Cancer Facts and Figures 2004

interested in proposals that combine the latest cutting-edge imaging technology with molecular probes, beacons, tracers, or contrast agents that hone in on specific targets within the body to allow for early detection/diagnosis of ovarian cancer. Studies investigating early detection/diagnosis of ovarian cancer in underserved populations are encouraged.

C. Award Mechanism Description: The intent of the HBCU/MI Collaborative Research Award is to provide research training and experience for HBCU/MI investigators involved in ovarian cancer or related research. A major aim of this award is to provide the opportunity for mentorship by supporting collaborations, specifically those between an HBCU/MI investigator conducting ovarian cancer or related research with little or no research funding and an established investigator in ovarian cancer research, to develop independent, competitive ovarian cancer researchers at HBCU/MI.

This award is intended to provide support for HBCU/MI faculty researchers with doctoral degrees that have little or no resources. The HBCU/MI Collaborative Research Award will provide an HBCU/MI investigator an opportunity to collaborate with and be mentored by well-established ovarian cancer researcher(s).

The HBCU/MI Collaborative Research Award proposals must address etiology/tumor biology, preclinical development of targeted therapies (excluding clinical trials), or early detection/diagnosis of ovarian cancer. All HBCU/MI Collaborative Research Award proposals must include preliminary data relevant to the proposed project.

III. AWARD INFORMATION

Funding for HBCU/MI Collaborative Research Awards can be requested for a maximum of $750,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. Projects requiring lower levels of funding may also be submitted. These funds can cover salary, expenses including research supplies, tuition for special training and/or education, consultation with scientific and/or technical experts, administrative and technical assistance, purchase of essential equipment or equipment rental, travel between the HBCU/MI and collaborator, and travel to scientific/technical meetings. The amount allotted for travel to scientific/technical meetings is $1,800 per year.

Collaborating investigators may receive up to 40% of the first-year costs; however, no more than 30% of the direct costs for the full award can be granted to the collaborating investigator during the lifetime of the award.

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. Depending on the number and quality of the applications, the OCRP expects to allot approximately $1.2M of the $10M FY05 OCRP appropriation to fund one HBCU/MI Collaborative Research Award.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be HBCU/MI doctoral-level faculty members. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible HBCU/MI institution.

Applicants may only submit one proposal per award mechanism as the Principal Investigator (PI) to the FY05 DOD OCRP.

B. Institutions: Eligible institutions are those approved as HBCU/MI by the Department of Education. Go to http://cdmrp.army.mil/funding/pdf/miocrp091404.pdf for a list of eligible HBCU/MI.

Eligible collaborating institutions include for-profit, non-profit, public, and private organizations.

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

D. Other Eligibility Criteria

1. Duplicate Submissions: Submission of the same research project to the FY05 OCRP under different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

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

3. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a lower global priority score.

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

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.

[2] Executive Orders 12876, 12900, and 13021

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.
- Proposal does not address one of the FY05 OCRP research areas of emphasis (etiology/tumor biology, preclinical development of targeted therapeutics [excluding clinical trials], or early detection/diagnosis of ovarian cancer).
- Applicant has submitted more than one proposal as the PI to one FY05 OCRP award mechanism.

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

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

V. PRE-PROPOSAL PREPARATION AND SUBMISSION INFORMATION

Investigators interested in applying for the HBCU/MI Collaborative Research Award must submit a pre-proposal. Pre-proposals will be screened to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full HBCU/MI Collaborative Research Award proposal will be sent to selected investigators no later than mid-November 2004. ***Do not submit a full HBCU/MI Collaborative Research Award proposal unless you receive a letter of invitation.***

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

The PI is responsible for uploading the following information:

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

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

- **Letter of Intent:** A Letter of Intent is not necessary for pre-proposal submission for the HBCU/MI Collaborative Research Award.

C. Pre-proposal Preparation

1. Format: All pre-proposals must be converted into a single electronic PDF file for electronic submission. Pre-proposals must be uploaded under the "Proposal Information" tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare pre-proposals for PDF submission, the instructions in this subsection must be followed carefully. Please note that pre-proposals do not require approval by the Contract Representative of the applicant's institution's Sponsored Programs Office (or equivalent).

The pre-proposal must be clear and legible and conform to the following guidelines. Please note that pre-proposals not adhering to these regulations will be withdrawn prior to pre-proposal screening.

Please Note New Format Requirements:

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

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

- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files, but applicants should keep in mind that some reviewers work from black and white printed copies. Applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Language: English.

2. Pre-proposal Title/Referral Page: No page limit. Complete the Title/Referral Page, which can be downloaded at https://cdmrp.org/programAnnouncements.cfm?prg=OCRP&prg_fy=2005. Complete each section as described:

a. Pre-proposal title (up to 160 characters).

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

c. First list the full name (first, middle initial, last) of the PI from the HBCU/MI. Then list the full name (first, middle initial, last) of the investigator from the collaborating institution.

d. Submitting Institution and Collaborating Institution.

e. Award mechanism: Type in "HBCU/MI Collaborative Research Award."

f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, please list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.

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

3. Pre-proposal Body: Start section on a new page; three-page limit. Pre-proposals should be written to describe a productive and substantive collaboration between the HBCU/MI investigator and the established investigator(s). Briefly describe the research project, educational experience, and mentored research environment that will foster a meaningful ovarian cancer research project in one of the three FY05 research areas of emphasis (etiology/tumor biology, preclinical development of targeted therapeutics [excluding clinical trials], or early detection/diagnosis of ovarian cancer). Describe how this award will provide an HBCU/MI investigator the opportunity to collaborate, train, and acquire the necessary research foundation, skills, and resources to become an independent, competitive ovarian cancer researcher. Provide details on the work to be conducted at the host HBCU/MI and the work to be conducted at the collaborating institution.

4. 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).

5. Biographical Sketches: Four-page limit per individual. Biographical sketches should be included for the participants at the applicant institution, participants at the collaborating institution, and each of the proposed key personnel, including all collaborating investigators. These documents are a critical component of the screening process. The Biographical Sketch form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

D. Electronic Pre-proposal Submission Requirements: Electronic submission of the pre-proposal is required. Pre-proposals will be accepted only as a single PDF file submitted through the CDMRP eReceipt system at https://cdmrp.org/proposals. Pre-proposals must be submitted on the CDMRP eReceipt system by the 5:00 p.m. Eastern time October 26, 2004 deadline.

Several steps are critical to successful pre-proposal submission.

- The Proposal Information must be submitted prior to submission of the pre-proposal. Applicants are encouraged to begin this part of the submission process early. During the full proposal submission process you will have an opportunity to edit the Proposal Information as needed.
- Although the applicant's Sponsored Programs Office (or equivalent) is not responsible for any part of pre-proposal submission, the Sponsored Programs Office (or equivalent) will be responsible for portions of the full proposal submission. Therefore, applicants are encouraged to begin coordinating with their Sponsored Programs Office (or equivalent) early, well in advance of full proposal submission.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time October 26, 2004 pre-proposal deadline.
- All components of the pre-proposal must be incorporated into one PDF file prior to upload.
- Some items to be included in the pre-proposal may need to be scanned. All scanned documents, including figures, should be scanned at a resolution of 300-400 dpi or less.

VI. PRE-PROPOSAL SCREENING INFORMATION

The OCRP Integration Panel (IP) will screen pre-proposals according to the criteria listed below:

- Is a clear and substantive collaboration being established between an HBCU/MI investigator and an established investigator(s) in ovarian cancer research? Does the established investigator(s) have a strong track record in acquiring funding in ovarian cancer research? Does the collaborating investigator have access to the facilities and equipment required to provide for this mentored research experience?
- Will this award provide the investigator at the HBCU/MI the opportunity to collaborate, train, and acquire the necessary research foundation, skills, and resources to become an independent, competitive ovarian cancer researcher?
- Does the proposed research project address one of the three FY05 research areas of emphasis (etiology/tumor biology, preclinical development of targeted therapeutics [excluding clinical trials], or early detection/diagnosis of ovarian cancer)?
- Did the PI adequately describe the amount as well as what part(s) of the research plan will be conducted at the different institutions?

Following completion of the pre-proposal screening, invitations to prepare a full HBCU/MI Collaborative Research Award proposal will be sent to selected investigators no later than mid-November 2004.

VII. INVITED PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. ***Do not submit a full HBCU/MI Collaborative Research Award proposal unless you receive a letter of invitation.***

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is not necessary for the HBCU/MI Collaborative Research Award.
- **Statement of Work (SOW) and Proposal Abstracts:** The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF file under the "Required Files" tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the "Required Files" tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form are each uploaded as separate PDF files under the "Required Files" tab.

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

- **The Contract Representative's contact information profile must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA) Required Documents:** The institution's currently negotiated "Rate Agreement," "Certifications and Assurances for Assistance Agreements," and the "Representations for Assistance Agreements" are to be uploaded as separate PDF files under the Contract Representative's "My Profile" tab.
- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration (or equivalent) must provide approval of all proposal components (Proposal Information, SOW, Abstracts, Proposal, Budget Information, and regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. Eastern time February 15, 2005. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as described in https://cdmrp.org/proposals. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution. The Proposal Information may be "Verified & Saved" for editing purposes until "Submit Final" for approval by their Sponsored Programs Office's (or equivalent's) representative.

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

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

As appropriate, the SOW should:

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

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

Programmatic review is based on the IP's review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the PI submit abstracts that fully describe the proposed work.

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

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

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale, specific aims of the study, study design, and significance of the proposed work to the Program's goals.

Use the outline below for preparing the structured technical abstract.

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

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

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

(1) What will be the ultimate applicability of the research?

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

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

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

E. Proposal

1. Format: All proposal components (proposal body, biographical sketches, publications, letters of support, etc.) must be converted into a single PDF file for electronic submission. Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following guidelines. Please note that proposals not adhering to these regulations will be withdrawn prior to peer review.

Please Note New Format Requirements:

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

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

- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files, but applicants should keep in mind that some reviewers work from black and white printed copies. Applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Language: English.

2. Title/Referral Page: No page limit. Complete the Title/Referral Page, which can be downloaded at https://cdmrp.org/programAnnouncements.cfm?prg=OCRP&prg_fy=2005. Complete each section as described:

a. Proposal title (up to 160 characters).

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

c. First list the full name (first, middle initial, last) of the PI from the HBCU/MI. Then list the full name (first, middle initial, last) of the investigator from the collaborating institution.

d. Submitting Institution and Collaborating Institution.

e. Award mechanism: Type in "HBCU/MI Collaborative Research Award."

f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.

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

3. Table of Contents/Checklist: Start section on a new page; one-page limit. Prepare a Table of Contents/Checklist, with page numbers, using the form provided at https://cdmrp.org/programAnnouncements.cfm?prg=OCRP&prg_fy=2005. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. **Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.**

4. Proposal Relevance Statement: Start section on a new page; one-page limit. Applicants should describe explicitly the plan for developing the collaboration between an HBCU/MI investigator and an established ovarian cancer researcher(s). Describe how the combination of training and relevance to ovarian cancer (etiology/tumor biology, preclinical development of targeted therapies, and/or early detection/diagnosis) will prepare the HBCU/MI investigator to establish an independent, competitive ovarian cancer research program.

5. Main Body: Start section on a new page; 10-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. The inclusion of promising preliminary data relevant to the proposed project is required for HBCU/MI Collaborative Research Award proposals. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Describe the proposed project using the outline provided below:

a. Background: Provide a brief statement of the ideas and reasoning behind the proposed collaboration. Proposal must present a clearly articulated plan for a mentored collaboration that focuses on etiology/tumor biology, preclinical development of targeted therapies (excluding clinical trials), and/or early detection/diagnosis of ovarian cancer.

b. Collaboration: A concise description of the proposed interaction between the HBCU/MI investigator and the collaborating investigator should be articulated. Describe explicitly how the collaboration will result in the development of a productive, independent ovarian cancer research program for the HBCU/MI investigator. Describe in

depth the proposed mentoring/ collaboration including any special seminar series, journal clubs, consultations, and technical assistance programs that are planned. Explain the pertinent qualifications of the collaborating investigator(s) and include the acquisition of funding for ovarian cancer research and experience in mentoring ovarian cancer researchers. List and describe the facilities that will be made available to the HBCU/MI investigator by the collaborating investigator.

c. Research Program: Describe the ideas and reasoning behind the proposed research project, including a summary of the research strategy, experimental design, and methodology. State the specific aims of the proposed research project. Briefly describe the methods to be used. Cite relevant literature references.

d. Communication: Outline the communication plan that will be used in this proposed collaboration. This plan should include frequent virtual and real-time interactions that support the collaboration and research project. If the HBCU/MI investigator and collaborator(s) are geographically far apart, explain how the communication and mentoring will be accomplished.

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

7. References: Start section on a new page; no page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

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

9. Existing/Pending Support: Start section on a new page; no page limit. List on a separate page the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel. If no support exists, state "none." Proposals submitted under this program announcement should not duplicate other funded research projects.

10. Facilities/Equipment Description: No page limit. Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate if government-owned facilities or equipment are proposed for use.

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

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

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

- The Statement of Eligibility form, signed by the Department Chair, Program Director, Dean, or equivalent official at the applicant institution indicating that the applicant holds a faculty position at an HBCU/MI and possesses a doctoral-level degree and therefore is an eligible applicant for this award.
- A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution assuring the commitment of the institution to the proposed collaboration. This letter should reflect the extent to which the institution will support the collaboration by relieving the investigator of his or her academic and/or clinical responsibilities to have additional time for research and mentoring, providing access to appropriate facilities, and providing opportunities for professional interactions with senior colleagues.
- A letter signed by the Department Chair, Program Director, Dean, or equivalent official at the collaborating institution describing the commitment of the collaborating investigator to the development/mentorship of the investigator at the HBCU/MI institution and the relevance of the proposed research and collaboration to ovarian cancer.
- Letters of support from any additional consultants/collaborators or institutions that will supply essential assistance to the proposed project describing their role in the research/collaboration.

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

13. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, the extra items will not be peer reviewed.

F. Budget Information: Budget Information includes the Detailed Cost Estimate form and Budget Justification form at https://cdmrp.org/programAnnouncements.cfm. Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for the HBCU/MI Collaborative Research Award can be requested for a maximum of $750,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. Projects requiring lower levels of funding may also be submitted. These funds can cover salary, expenses including research supplies, tuition for special training and/or education, consultation with scientific and/or technical experts, administrative and technical assistance, purchase of essential equipment or equipment rental, travel between the HBCU/MI and collaborator, and travel to scientific/technical meetings. The amount allotted for travel to scientific/technical meetings is $1,800 per year.

Collaborating investigators may receive up to 40% of the first-year costs; however, no more than 30% of the direct costs for the full award can be granted to the collaborating investigator during the lifetime of the award.

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

Costs proposed must conform to the following regulations and principles:

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

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

a. Personnel

i. Name: Starting with the PI, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.

ii. Role on Project: Identify the role of each individual listed on the project. Describe his or her specific functions in the Budget Justification section of the Detailed Cost Estimate form.

iii. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the Budget Justification section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

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

v. Percentage of Effort on Project: The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

vi. Salaries Requested: Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

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

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

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

c. Major Equipment: It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed $5,000.

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

e. Travel Costs: Travel costs to scientific/technical meetings may not exceed $1,800 per year.

f. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

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

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

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

i. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be

disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the Budget Justification section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should equal the amount previously entered online in the Proposal Information https://cdmrp.org/proposals.

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

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

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

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

I. Submission Date and Time: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by the deadline. If your proposal is either incomplete or not approved electronically before the deadline, it will not be considered for review. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time February 15, 2005 deadline.

The timeline for the HBCU/MI Collaborative Research Award is:

Pre-proposal Submission Deadline:	**5:00 p.m. Eastern time October 26, 2004**
Pre-proposal Screening:	Early November 2004
Full Proposal Invitations:	Mid-November 2004
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time February 15, 2005**

Peer Review:	April 2005
Programmatic Review:	July 2005
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after programmatic review
Award Start Date:	Anticipated between September 2005 and December 2005

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

Several steps are critical to successful proposal submission:

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in the Proposal Information.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time February 15, 2005 deadline.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Detailed Cost Estimate form and the Budget Justification form. Budget Information must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VIII. INVITED PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier review process for proposal evaluation. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit as well as overall program goals.

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

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

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see below). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

3. Programmatic Review: The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to maintain a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the peer review

summary statements and the proposal abstracts. SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

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

B. Review Criteria

1. **Peer Review:** HBCU/MI Collaborative Research Award proposals will be evaluated according to the following criteria:

   - **Applicant:** Does the HBCU/MI applicant's previous training history, prior research experience, and publication record indicate promising achievements in ovarian cancer research or a related field? Will the collaboration offer a valuable opportunity to further develop necessary experience to advance the PI's capability to develop an independent research program in ovarian cancer? Is there evidence demonstrating that the HBCU/MI applicant will be released of duties to pursue this research?
   - **Collaborating Investigator:** Does the collaborating investigator have the background, qualifications, experience, and record in ovarian cancer research to develop a productive collaboration with the applicant? Does the collaborating investigator have a strong record of funding for ovarian cancer research? Do the HBCU/MI and collaborating investigators propose to sustain an interactive, ongoing partnership? Is there evidence demonstrating that the collaborating investigator(s) will be released of duties to pursue this research?
   - **Research Plan:** Do both the HBCU/MI and collaborating investigators substantially contribute to the planned project? Are the conceptual framework, concepts, hypothesis, design, methods, and analyses of the research adequately developed? Is the preliminary data relevant to the proposed project? Is the research project of sufficient depth and duration to lead to publication of results in peer-reviewed literature? How do the HBCU/MI and collaborating investigators propose to sustain the interactive environment necessary for the development of an effective mentoring program? Did the PI adequately describe the amount as well as what part(s) of the research plan will be conducted at the different institutions?
   - **Disease Relevance:** Do the proposed research and collaboration clearly focus on ovarian cancer etiology/tumor biology, preclinical development of targeted therapies, and/or early detection/diagnosis? Does the HBCU/MI make a convincing case for his or her commitment to ovarian cancer research?
   - **Budget:** Is the budget reasonable for the work proposed? Does the HBCU/MI receive at least 70% of the direct costs for the proposed period of performance for use on research related to establishing an ovarian cancer research program?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to maintain the

OCRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation; and
- Program portfolio balance with respect to the research areas of emphasis (etiology/tumor biology, preclinical development of targeted therapeutics [excluding clinical trials], early detection/diagnosis).

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

IX. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tier evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in August 2005.

B. Administrative Requirements: All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for the award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and DOD Grant and Agreement Regulations). *Any organization requesting receipt of an award from this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.*

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

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

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

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiations, the Office of Surety, Safety and Environmental will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use submitted upon request to ensure that Army regulations are met.

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

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

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

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

4. Research Involving Animal Use: Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02AnimalAppendix.doc.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: (See Subsections VII.G and V.H for information pertaining to the submission of human subjects and/or human anatomical substances documents or cadavers.) In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances or cadavers, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Human Subjects Protection branch. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. For example:

- Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at
https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc
An informed consent form template can be located at
https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

6. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written approval from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward these written approvals directly to the applicant.

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

- **Research Progress Report Requirements:** Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project.
- **Fiscal Report Requirements:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

X. OTHER INFORMATION

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

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

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

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

E. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq.[3]), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

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

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

XI. ACRONYM LIST

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