

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: Ovarian Cancer Research Program (OCRP) Concept Award.

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

C. Funding Opportunity Number: W81XWH-06-OCRP-CA.

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 (OC06-CA)
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 difficulties 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.

For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4).¹ Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Concept Award is one of the mechanisms of the Ovarian Cancer Research Program (OCRCP), which was established in FY97 to promote innovative research directed toward eliminating ovarian cancer. Appropriations for the OCRCP from FY97 to FY05 totaled \$91.7 million (M). During this time, the OCRCP received 1,098 proposals and funded 108 projects. This is the first year in which Concept Awards have been offered as part of the OCRCP. The FY06 appropriation is \$10M.

B. Program Objectives: The overall goal of the FY06 OCRCP is to eliminate ovarian cancer by stimulating and supporting innovative research in ovarian cancer. The OCRCP seeks to attract independent investigators, including those from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) institutions, to initiate research focused on ovarian cancer. *Within this context, the key initiatives of this announcement are to support*

¹Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

innovative technology, hypotheses, or experimental results that will drive the field forward.

The OCRP anticipates that this approach will lead to the exploration of new ideas and perspectives on the prevention, detection, diagnosis, and treatment of ovarian cancer. The FY06 OCRP encourages proposals focusing on epithelial ovarian carcinoma because it accounts for about 70% of ovarian cancers. Proposals addressing primary peritoneal carcinoma, a disease with a clinical course similar to epithelial ovarian carcinoma, are also welcome.

Although the OCRP is interested in many research disciplines and 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 *FY06 OCRP is focusing on only the following three research areas of emphasis as applied to either epithelial ovarian carcinoma or primary peritoneal carcinoma. Proposals on ovarian cancer prevention that fit within the context of these areas of emphasis will be considered. Proposals that do not address at least one of these FY06 research areas of emphasis will be administratively withdrawn and will not be considered for funding.*

1. Etiology/Tumor Biology: Elucidation of the causes of ovarian cancer and the mechanisms of initiation, tumor growth, angiogenesis, invasion, progression, and metastasis is needed. Such basic research is an essential prerequisite for the development of new risk assessment and 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, particularly those pathways that are key targets in ovarian cancer.

2. Preclinical Development of Targeted Therapeutics (Excluding Clinical Trials): The OCRP is interested in preclinical development and validation of new and effective targeted agents for the prevention and treatment of ovarian cancer. For FY06, the OCRP is *not* interested in projects proposing traditional chemotherapy trials and will fund only projects proposing preclinical work within this FY06 research area of emphasis. No clinical trials of therapeutics will be funded.

3. Early Detection/Diagnosis: The OCRP encourages research from all scientific disciplines that will facilitate earlier, easier, and more accurate physician detection and diagnosis of ovarian cancer, and seeks proposals for developing novel imaging technologies and novel applications of existing technologies. Research using spectroscopic and tomographic techniques for the imaging of physical, biological, or molecular markers of ovarian cancer is encouraged. These techniques include, but are not limited to, optical (fluorescence, UV, raman/IR) imaging, magnetic resonance-based spectroscopies, and nuclear imaging methods. Proposals for the identification or synthesis of ovarian cancer-specific imaging probes are welcome. The OCRP encourages proposals on the identification of serum or cell biomarkers for the detection and diagnosis of ovarian cancer. Studies investigating early detection and diagnosis of ovarian cancer in underserved populations are also encouraged.

C. Award Mechanism Description: The intent of the OCRP Concept Award is to spark new ideas and encourage the exploration of innovative concepts or theories in ovarian cancer. The

proposed research should provide a catalyst to challenge or expand current thinking and approaches in ovarian cancer research. These awards provide investigators with the opportunity to pursue serendipitous observations and underexplored hypotheses. It is anticipated that research completed through a Concept Award will provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for future research leading to advances in prevention, detection, diagnosis, or treatment of ovarian cancer. Presentation of preliminary data is not consistent with the intent of this award mechanism.

- Innovation and impact on the field of ovarian cancer research are significant features of the Concept Award.

Because these awards are designed for preliminary investigations, projects involving human subjects or human biological substances will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

III. AWARD INFORMATION

Funding for Concept Awards can be requested for a maximum of \$75,000 for direct costs over the entire performance period. The performance period can be requested for up to 18 months. In addition, indirect costs should be added as appropriate. Projects requiring lower levels of funding may also be submitted. These funds can cover salary, research supplies, and travel to scientific/technical meetings. The nature of the OCRP does not allow for renewal of grants or supplementation of existing grants.

Approximately \$1M of the \$10M FY06 OCRP appropriation is available to fund 10 Concept Awards, depending on the number and quality of proposals received.

IV. ELIGIBILITY INFORMATION

A. Applicants: All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution 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 include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from HBCU/MI.

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

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

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

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

²Executive Orders 12876, 12900, and 13021

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. Proposals will be evaluated according to peer and programmatic review criteria in [Section VI](#). Reviewers will be blinded to the identity of the applicant and applicant’s institution.

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	Enter contact information for the applicant and the Contract Representative.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	None. Not applicable for this award
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/SOW	Typed or Cut and Paste	Technical Abstract, Public Abstract, Impact Statement are not required; type N/A into the data fields. Enter the SOW in a separate data field.
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 as PDF files.

2. Contract Representative’s 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	Enter appropriate information before electronic approval of all submission components.
USAMRAA ^a -Required Documents	My Profile for the CR	PDF	Upload the 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, Abstracts/Impact/SOW, and Required Files <i>before</i> the submission deadline of 5:00 p.m. Eastern time, March 21, 2006.

^aUS Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the “Required Files” tab of the CDMRP eReceipt 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 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 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:** Not allowed for Concept Award submissions.
- **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 electronically captured 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.
- Cost Estimate and Budget Justification form is missing.
- Proposal is incomplete after the deadline.
- Applicant and/or institution names are included in the proposal body.

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.

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 before electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

D. 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.

- **Letter of Intent:** A Letter of Intent is not required for this award mechanism.
- **Title/Referral Page:** The Title/Referral Page is not applicable for this award mechanism.

E. Proposal Contacts: 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.

F. Collaborators and Conflicts of Interest (COI): Not applicable to this award mechanism as reviewers are blinded to the identity of the applicant and applicant’s institution.

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

H. Impact Statement: An Impact Statement is not required for this award mechanism. The data field must be completed by typing “N/A.”

I. Statement of Work (SOW) – 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 system. Applicants can type the SOW into the data field or “cut and paste” it from a word processing application. *Spell out all Greek letters, other non-English letters, and symbols.* Sample SOWs can be found at <https://cdmrp.org/samples.cfm>. The SOW will be used only during award negotiations.

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

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 number of animal subjects projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

J. Proposal Main Body: Two-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

Clearly explain how the proposed research is innovative and what impact it will have on ovarian cancer. Presentation of preliminary data is not required. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature.

Due to the blinded nature of the review process (see [Subsection VI.A](#)), references to the applicant or the institution in the proposal body are prohibited and will be cause for administrative withdrawal of the proposal.

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

Describe the proposed project using the following outline:

- 1. Background:** Present the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this project.
- 2. Specific Aims:** Concisely state the project's specific aims.
- 3. Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls.
- 4. Innovation:** State concisely how the proposed research uses innovation to advance the prevention, detection, diagnosis, or treatment of ovarian cancer.
- 5. Impact:** Describe the impact of these studies on the concepts or methods that drive the field of ovarian cancer research. In non-technical terms, state how the results of the proposed research will offer an original and important contribution in ovarian cancer research.

K. 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.

A maximum of five references are to be included in this section. List up to five 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).

L. Budget Information: Applicants must complete the [Concept Award Cost Estimate and Budget Justification form](#) at and upload it as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

- 1. Funding Restrictions:** Funding for Concept Awards can be requested for a maximum of \$75,000 for direct costs over the entire performance period. The performance period can be requested for up to 18 months. In addition, indirect costs should be added as appropriate. Projects requiring lower levels of funding may also be submitted. The funds can cover salary, research supplies, and travel to scientific/technical meetings.

The travel allotment is \$1,800 per year to attend scientific/technical meetings.

- 2. Concept Award 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.*** All costs must be entered in U.S. dollars.

The [Concept Award Cost Estimate and Budget Justification form](#) must be uploaded as a PDF file under the “Required Files” tab in the CDMRP eReceipt system.

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.

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 Concept Award Cost Estimate and Budget Justification form.

a. Personnel

- i. Name:** Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. ***The applicant must be identified as the Principal Investigator of the proposal.***
- ii. Role on Project:** Identify the role of each participant listed.
- 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 unless otherwise noted. 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 research proposals for funding. List the percentage of each appointment to be spent on this project for each key staff member identified on the budget form. Include the percentage of effort of all unpaid collaborators and consultants.

vi. Salaries Requested: Enter the salaries in whole U.S. 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 for all sponsors by the applicant's organization. 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: Provide the names and organizational affiliations of all consultants whether or not funds are requested.

c. Major Equipment: Funding for this award cannot be used for the purchase of equipment.

d. Materials, Supplies, and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines (which must be exempt under 32 CFR 219.101(b)(4)) are to be purchased, state the source and the description.

e. Travel Costs: The travel allotment is \$1,800 per year for travel to scientific or technical meetings.

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. 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.

g. 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.

h. 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.

i. Total Costs: Direct costs, indirect costs, and the total cost for the entire proposed performance period should equal the amount entered in the "Required Files" tab at <https://cdmrp.org>.

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

4. Federal Agency Financial Requirement: Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

Start the plan on a new page at the end of the Budget Information section. The Federal Agency Financial Plan must be uploaded as part of the budget information prior to the receipt deadline of **5:00 p.m. Eastern time, March 21, 2006.**

M. 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 (for example, documents supporting research exempt under 32 CFR 219.101(b)(4) or Research Involving Animals) with the proposal. The applicant should provide these documents to the USAMRMC only upon request.

N. 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 at the applicant’s institution. 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.

O. 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 eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, March 21, 2006 deadline.

The timeline for the Concept Award is:

Online Proposal Information:	Required prior to proposal submission
<i>Proposal Submission/Approval Deadline:</i>	<i>5:00 p.m. Eastern time, March 21, 2006</i>
Peer Review (First Tier):	May 2006
Programmatic Review (Second Tier):	July 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

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

Several steps are critical to successful proposal submission:

- The Proposal Information must be “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, March 21, 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 Concept Cost Estimate and 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.

VI. 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 differ fundamentally. The first tier is a scientific peer review of proposals against established criteria for determining 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 and overall goals of the Program.

This will be a blinded review process; the applicant and institution names will not be provided during either peer or programmatic review.

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 peer review by bringing the patient perspective to the assessment of science and the relevance of the research.

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 on the two-page Concept Award proposal and the peer review evaluations.

B. Review Criteria

1. Peer Review: Concept Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

- **Innovation and Novelty of Concept**
 - How the proposed concept is innovative.
 - That the concept is new or in the initial stage of development.
 - How the concept will give rise to a testable hypothesis if successful.
- **Impact**
 - How the study addresses a problem critical to ovarian cancer research.
 - How the project will lead to an original and important contribution to the prevention, detection, diagnosis, and/or treatment of ovarian cancer.
 - What impact this study will have on the concepts or methods that drive the field.
- **Research Strategy**
 - How the scientific rationale and logical reasoning support the project and its feasibility.

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

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

- Adherence to the intent of the award mechanism, and
- The two-page Concept Award proposal.

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.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: Each applicant will receive notification of the award status of his or her proposal. Applicants can expect to receive notification approximately four weeks after programmatic review. Peer review summary statements will not be provided to the applicants.

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, 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) 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>.*

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

For Concept Awards, no changes in the institution or the SOW will be allowed once the proposal has been submitted.

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 proposed SOW and associated budget may be required as part of the negotiation process. Technical and public abstracts will be requested at this time.

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>.

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

a. Restrictions: Projects involving human subjects or specimens will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4) or involve the use of only commercially available anonymized specimens.

In addition to local Institutional Review Board (IRB) approval or determination of exempt status, a second-level review is required by the DOD for concurrence with the exempt status. This second review is conducted by the USAMRMC Office of Research Protection. Documents supporting the exempt status of the project will be requested at a later date. These documents will include documentation of local IRB determination of exempt status and the completed USAMRMC Office of Research Protections Claim of Exemption Form. For studies using only commercially available specimens, the USAMRMC Office of Research Protections Claim of Exemption Form will be requested.

See [Subsection V.M](#), “Regulatory Requirements,” for information pertaining to the submission of documents related to the use of human biological substances.

Specific requirements for research involving human biological substances can be found at <https://mrmc.detrick.army.mil/rodorphrpo.asp>.

b. 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* if the research is in compliance with 45 CFR 46, Subpart B; 42 USC 289g through 289g-2³; 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* when 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 that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

Please note 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.

³Title 42 United States Code, Sections 289g through 289-2

6. Award/Regulatory Approval: The applicant may not use, employ, or subcontract for the use of any exempt human anatomical substances 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 mechanism. (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 a final report that details the scientific 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. 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.

VIII. 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.

IX. ACRONYM LIST

AVI	Audio Video Interleave
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
COI	Conflict of Interest
CR	Contract Representative
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
hES	Human Embryonic Stem
HSRRB	Human Subjects Research Review Board
IR	Infrared
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group

M	Million
MB	Megabytes
MPEG	Moving Picture Experts Group
NIH	National Institutes of Health
OCR	Ovarian Cancer Research Program
OMB	Office of Management and Budget
PDF	Portable Document Format
SOW	Statement of Work
TIFF	Tagged Image File Format
URL	Uniform Resource Locator
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
URL	Uniform Resource Locator
USC	United States Code
UV	Ultraviolet
WAV	Wave