Program Announcement

Defense Health Program Department of Defense Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Ovarian Cancer Academy Award—Early-Career Investigator

Funding Opportunity Number: W81XWH-12-OCRP-OCA Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), April 17, 2012
- Invitation to Submit an Application: May 2012
- Application Submission Deadline: 11:59 p.m. ET, July 18, 2012
- **Peer Review:** September 2012
- **Programmatic Review:** November 2012

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Ovarian Cancer Research Program (OCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. Appropriations for the OCRP from FY97 through FY11 totaled \$180.45 million (M). The FY12 appropriation is \$16M. The overall goal of the FY12 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research.

B. Award Information

The OCRP Ovarian Cancer Academy, which was initially created in FY09, is intended to be a unique, interactive virtual academy providing intensive mentoring, national networking, and a peer group for junior faculty. The overarching goal of the Ovarian Cancer Academy is to develop successful, highly productive ovarian cancer researchers in a collaborative research training environment. The current Ovarian Cancer Academy is a virtual career development and research training platform consisting of seven Early-Career Investigator/Designated Mentor pairs from different institutions and one Academy Dean. The Academy Dean serves as a resource for the Early-Career Investigators and Mentors, assesses the progress of the Early-Career Investigators, and facilitates communication and collaboration among all of the Early-Career Investigators and Mentors.

This FY12 Funding Opportunity is soliciting additional Early-Career Investigators to join the existing Academy. Applications to this award mechanism must be submitted by the Early-Career Investigator as the Principal Investigator (PI).

Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to come from the ovarian cancer research field. *Clinical trials are not allowed under this mechanism*.

The Early-Career Investigator, who will be the PI of the application, must be in the early stage of his/her career. This award provides the Early-Career Investigator with funding, networking opportunities, and research experience necessary to develop and sustain a successful, independent career at the forefront of ovarian cancer research. This award also provides support and protected time for the Early-Career Investigator for 5 years of intensive research under the guidance of a Designated Mentor experienced in ovarian cancer research. Although the Ovarian Cancer Academy will serve as a conduit to share knowledge and research experience among all academy members, the Early-Career Investigator and his/her Designated Mentor will be responsible for developing the Early-Career Investigator's career development plans and for designing and executing the proposed research. The Early-Career Investigator must clearly articulate his/her commitment to a career as an ovarian cancer researcher.

The Designated Mentor must have a strong record of mentoring and training early-career investigators. In addition to being a Designated Mentor to an Early-Career Investigator at his/her institution, the Mentor must agree to serve as a secondary Mentor to another Ovarian Cancer Academy Early-Career Investigator who may or may not be at the Designated Mentor's institution.

Biennially, a 3-day conference developed by the OCRP program staff with input from the Academy Dean will be held for presentations, networking, and workshops. In alternate years, a 1-day workshop will be held.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

C. Eligibility Information

Early-Career Investigator:

- Must be within the first 3 years of his/her first faculty position (or equivalent) at the time of award. The first faculty position (or equivalent) may be either tenure-track or non-tenure-track.
- May be research or physician-scientists.
- Must have an institutional commitment of at least 50% protected time.
- Must receive institutional support of \$50,000 per year (e.g., supplies, staff, salary, research funds, and start-up package).

Designated Mentor:

- Must be at the same institution as the Early-Career Investigator.
- Must be an independent, established ovarian cancer researcher.
- Must have ovarian cancer research funding (past and present).
- Must have a record of ovarian cancer publications in peer reviewed journals.
- Must demonstrate a commitment (at least 10% effort for mentoring and participating in off-site Academy activities) to develop and sustain the Early-Career Investigator's independent career in ovarian cancer research.

Cost sharing/matching is an eligibility requirement. The institution must commit to protecting at least 50% of the Early-Career Investigator's time and must provide institutional support of \$50,000 per year (e.g., supplies, staff, salary, research funds, and start-up package).

Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$750,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

• Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel to the annual 1-day conference with Academy Dean and other Academy members (Early-Career Investigator and Designated Mentor)
- Travel to biennial 3-day conference with the OCRP staff, Academy Dean, and other Academy members (Early-Career Investigator and Designated Mentor)

May be requested for (not all-inclusive):

- Salary (Early-Career Investigator, Designated Mentor, research staff)
 - Maximum allowable funding for the Designated Mentor is \$30,000 per year in direct costs
- Research-related subject costs
- Equipment
- Tuition for training and/or other educational opportunities
- Consultation with scientific and/or technical experts (e.g., statisticians, editors)
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings
- Costs associated with participating in the virtual academy (e.g., hardware and/or software for audio- or video-teleconferencing or web-based communications)

The CDMRP expects to allot approximately \$2.4M of the \$16M FY12 appropriation to fund approximately two Ovarian Cancer Academy Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<u>https://cdmrp.org/</u>) and (2) application submission through Grants.gov (<u>http://www.grants.gov/</u>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<u>http://www.grants.gov/</u>) basic search using the Funding Opportunity Number: W81XWH-12-OCRP-OCA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<u>https://cdmrp.org/</u>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at <u>help@cdmrp.org</u> or 1-301-682-5507.

A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- Application Information Tab 1
- Application Contacts Tab 2
- Collaborators and Conflicts of Interest (COI) Tab 3

FY12 OCRP Integration Panel (IP) members should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

• Required Files – Tab 4

Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The Preproposal Narrative should include the following:

Describe the Early-Career Investigator's (PI on this award) career goals in ovarian cancer research. Briefly describe the career development plan and how the Designated Mentor will assist the Early-Career Investigator in not only developing, but also sustaining, his/her career as an independent ovarian cancer researcher. Briefly describe the proposed research idea in ovarian cancer that will be supported by this award, as well as the ability of the Early-Career Investigator to conduct the research or the relevant training that will be obtained to accomplish the project. Describe the Early-Career Investigator's commitment to participating in the Ovarian Cancer Academy.

Summarize how the proposed research and career development experience will promote an independent, sustainable career in ovarian cancer research.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- PI Biographical Sketch (four-page limit). The biographical sketch should support the personal statement.
- Designated Mentor Biographical Sketch (four-page limit).
- Submit Pre-Application Tab 5

This tab must be completed for the pre-application to be accepted and processed by the CDMRP.

Other Documents Tab

No additional documents are required.

Pre-Application Screening

• Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Department of Defense (DoD) and the OCRP, pre-applications will be screened based on the following criteria:

- The Early-Career Investigator's (PI) career goals in ovarian cancer research.
- The proposed research and career development plans.
- How the Designated Mentor will assist the Early-Career Investigator.
- The Early-Career Investigator's commitment to participating in the Ovarian Cancer Academy.

Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

Pre-application notification dates are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received notification of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<u>http://www.grants.gov/</u>). For the Ovarian Cancer Academy Award, additional application components are also required and should be submitted as directed below.

Grants.gov application package components: For the Ovarian Cancer Academy Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

- **1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 2. Attachments Form
 - Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf."
 - **Early-Career Investigator's Career Goals** (one-page limit recommended): Describe the Early-Career Investigator's (PI on this award) career goals in ovarian cancer research and how the proposed research and career development experience will promote an independent, sustainable career. Discuss the Early-Career Investigator's career plans after the completion of this award.
 - Career Development and Sustainment Plan (one-page limit recommended): Describe the career development plan, which may include conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Explain how this career development plan will allow the Early-Career Investigator to obtain independent ovarian cancer research funding and publish in peer reviewed journals, thereby sustaining an independent career at the forefront of ovarian cancer research. Discuss how the Designated Mentor will assist the Early-Career Investigator in not only developing, but also sustaining his/her career as an independent ovarian cancer researcher. Explain how the career development plan is supported by the environment; this should include a description of ongoing ovarian cancer research and available resources at the institution. Outline how the Early-Career Investigator's progress of achieving and sustaining a productive career in ovarian cancer research.
 - **Research Project** (six-page limit recommended): Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to come from the ovarian cancer research field. Address potential problem areas and present alternative methods and approaches. If the proposed project uses human subjects or human biological samples, include a detailed plan for the recruitment of subjects or the acquisition of samples. The research description should also describe the ability of the Early-Career Investigator to conduct the research or the relevant training that will be obtained to accomplish the project. This award may not be used to conduct clinical trials.
 - **Integration of Career Development and Research** (one-page limit recommended): Describe how the career development plan and research project are integrated and how they will contribute to preparing the Early-Career Investigator for an independent, sustainable career in ovarian cancer research.

- **Commitment to the Ovarian Cancer Academy** (one-page limit recommended): Describe the Early-Career Investigator's commitment to participating in the Ovarian Cancer Academy, to include networking with the other Early-Career Investigator/Designated Mentor pairs and the Academy Dean.
- Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.
 - References Cited : List the references cited (including URLs if available) in the project narrative 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).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included. Extra items will not be reviewed.
 - Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
 - For the Early-Career Investigator application, the institution must demonstrate a commitment to the Early-Career Investigator through at least 50% protected time. Describe in detail, the institutional support of \$50,000 per year (e.g., supplies, staff, salary, research funds, start-up package) for 5 years that the institution will provide to the Early-Career Investigator.
 - Designated Mentor's Letter for the Early-Career Investigator application (threepage limit):
 - The Designated Mentor's letter should describe the Early-Career Investigator's background and potential to become an independent ovarian cancer researcher. Explain how this award will enhance the Early-Career Investigator's capabilities to sustain a career in ovarian cancer research.
 - Describe the Designated Mentor's background and experience in ovarian cancer research, success in acquiring funding in ovarian cancer research,

and record of mentoring and training young investigators. Specify the commitment of the Designated Mentor (at least 10% effort) and his/her staff to the Early-Career Investigator's professional development and career sustainment. Describe the specific resources that will facilitate success for the Early-Career Investigator.

- Describe the Designated Mentor's commitment to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Dean. Describe the Designated Mentor's commitment and time to serve as a secondary mentor to another Early-Career Investigator in the Ovarian Cancer Academy.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."

The technical abstract is used by peer and programmatic reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

- Training Plan
 - Summarize how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the Early-Career Investigator's independent career at the forefront of ovarian cancer research.
 - Describe how the proposed research project will train the PI to make valuable contributions to ovarian cancer.
- Research Plan
 - Background: Present the ideas and reasoning behind the proposed work.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide supporting evidence or rationale.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design, including appropriate controls.
- Impact: Describe how the proposed research will make important contributions toward the goal of eliminating ovarian cancer.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."
 - Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.

- Describe the PI's career goals in ovarian cancer research.
 - How does the research and training plan support the PI in attaining these goals?
- Describe the ultimate applicability of the research.
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of ovarian cancer research?
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.
- Attachment 6: Impact Statement (one-page limit): Explain how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the Early-Career Investigator's independent career at the forefront of ovarian cancer research. Describe how the proposed research will make important contributions toward the goal of eliminating ovarian cancer.
- **3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
 - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
 - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
 - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
 - Include the Designated Mentor's Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
 - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
 - Include the Designated Mentor's Current/Pending Support (no page limit): Upload as "Suppost_LastName.pdf."
- **4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."
- **5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

6. R & R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the <u>title page</u> of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DoD and OCRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the meritbased selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are listed in decreasing order of importance:

• Early-Career Investigator

- How the Early-Career Investigator's record of accomplishments demonstrates his/her potential for becoming an independent investigator in ovarian cancer research.
- How the Early-Career Investigator's career goals are consistent with a commitment to pursuing and sustaining a career as an ovarian cancer researcher.
- Whether the Early-Career Investigator meets the appropriate eligibility requirements.
- Whether the level of effort of the Early-Career Investigator meets the requirements (at least 50% protected time) and is appropriate for successful conduct of the proposed work.
- How the Designated Mentor's letter supports the Early-Career Investigator's potential for a productive, sustainable, and independent career in ovarian cancer research.
- How the Early-Career Investigator is committed to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Dean.

• Career Development and Sustainment Plan

- How well the Early-Career Investigator has outlined an individualized Career Development and Sustainment Plan that is consistent with the Ovarian Cancer Academy and the Early-Career Investigator's research goals.
- How the Career Development and Sustainment Plan will contribute to the overall professional development of the Early-Career Investigator and prepare the Early-Career Investigator for an independent, productive career in ovarian cancer research.
- Adequacy of the plans for monitoring and evaluating the Early-Career Investigator's progress in becoming an independent investigator.

• Designated Mentor

- How the Designated Mentor's background, research experience, and funding history support the Early-Career Investigator's career development needs and transition to independence.
- Whether the Designated Mentor is an independent, established ovarian cancer researcher with ovarian cancer research funding (past and present) and a record of ovarian cancer publications in peer reviewed journals.

- How the Designated Mentor's track record in preparing investigators for careers in ovarian cancer research indicates the potential for successful mentorship and development of the Early-Career Investigator as an independent investigator.
- How the quality of the Career Development and Sustainment Plan and research project suggests that the Designated Mentor has provided appropriate guidance.

• Research Strategy and Feasibility

- How the scientific rationale supports the research project and its feasibility as demonstrated by a review and analysis of the literature and relevant preliminary data (preliminary data do not need to come from the ovarian cancer research field).
- How well the hypotheses or objectives, experimental design, methods, and analyses are developed and support completion of the aims.
- How well the Early-Career Investigator acknowledges potential problems and addresses alternative approaches.

• Impact

- How the proposed research and Career Development and Sustainment Plan will facilitate and sustain the Early-Career Investigator's independent career at the forefront of ovarian cancer research.
- How the proposed research makes an original and important contribution to the goal of eliminating ovarian cancer.

• Resources

- How the proposed research project and career development of the Early-Career Investigator is supported by the availability of facilities, equipment, staff, interaction with research colleagues, and other resources.
- Whether there are commitments from the institution of at least 50% protected time and institutional support of \$50,000 per year (e.g., supplies, staff, salary, research funds, start-up package) for 5 years.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

• Budget

• Whether the budget is appropriate for the proposed research, career development, and participation with the Ovarian Cancer Academy, and within the limitations of this Program Announcement/Funding Opportunity.

• Application Presentation

• To what extent the writing, clarity, and presentation of the application components influenced the review.

- 2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and OCRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:
 - Ratings and evaluations of the peer reviewers
 - Relative impact
 - Program portfolio balance or composition
 - Adherence to the intent of the award mechanism
 - Programmatic relevance

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

All application review dates and times are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

• Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative is missing.
- Project Narrative exceeds page limit.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Submission of an application for which a letter of invitation was not received.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY12 OCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY12 OCRP IP members can be found at http://cdmrp.army.mil/ocrp/panels/panels12.shtml.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements. In addition to written progress reports, oral presentations may be requested.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: <u>help@cdmrp.org</u>

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: <u>support@grants.gov</u>

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application

package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
Attachments Form	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
Research & Related	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
Senior/Key Person Profile (Expanded)	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	