I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Ovarian Cancer Academy – Early-Career Investigator Award

Announcement Type: Initial

Funding Opportunity Number: HT942524OCRPOCAECI

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 14, 2024
- Invitation to Submit an Application: June 17, 2024
- Application Submission Deadline: 11:59 p.m. ET, August 6, 2024
- End of Application Verification Period: 5:00 p.m. ET, August 9, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** December 2024

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Ovarian Cancer Research Program (OCRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the OCRP in FY97 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the OCRP from FY97 through FY23 totaled \$496.45 million (M). The FY24 appropriation is \$45M.

The mission of the OCRP is to support patient-centered research to prevent, detect, treat, and cure ovarian cancer to enhance the health and well-being of Service Members, Veterans, their Family members, and all women impacted by this disease.

II.A.1. Award History

The OCRP Ovarian Cancer Academy – Early-Career Investigator (OCA-ECI) Award mechanism was first offered in FY09. Since then, 168 OCA-ECI Award applications have been received, and 39 have been recommended for funding.

II.B. Award Information

Initially created in FY09, the OCRP Ovarian Cancer Academy (OCA) is a unique, interactive virtual academy providing intensive mentoring, national networking, collaborations, and a peer group for junior faculty. The overarching goal of the OCA is to develop successful, highly productive ovarian cancer researchers in a collaborative research and career development environment.

The OCA is a virtual career development and research training platform that consists of Early-Career Investigators (ECIs), their Designated Mentors from different institutions, and an Academy Dean and Assistant Dean. The OCA-ECI Award is not a traditional career development award; the ECI is expected to participate in monthly webinars and annual workshops and to communicate and collaborate with other members of the Academy (other ECIs, Mentors, the Dean and Assistant Dean) as well as with the advocacy community. Since its inception, the Academy's ECIs have presented at and chaired sessions for ovarian cancerspecific symposia and served on symposia review committees. They have also served as peer reviewers for the Department of Defense (DOD) OCRP and other funding agencies.

The OCA Leadership (the Dean and Assistant Dean) serves as a resource for the ECIs and Mentors, assessing the progress of the ECIs and facilitating communication and collaboration among all of the ECIs and Mentors, as well as with national research and advocacy communities. In addition to fostering the scientific development, the OCA, through its Leadership, provides for professional and leadership development of the ECIs to include skills and competencies needed to fund and manage a productive laboratory. Information about the OCA is available through its website, <u>https://www.med.upenn.edu/dodovariancanceracademy/</u>.

This FY24 program announcement/funding opportunity is soliciting additional ECIs to join the existing OCA. This award mechanism enables the ECI (the investigator named as the Principal Investigator [PI] on the application) to pursue an ovarian cancer project that may involve basic, translational, and/or clinical research. *The Designated Mentor is not required to be at the same institution as the ECI*.

The OCRP encourages applications from ECIs whose ability to commit to conducting ovarian cancer research is limited by minimal resources or a lack of resources, such as a qualified Designated Mentor at their institution, access to ovarian cancer research tools, opportunities for establishing collaborations, or other obstacles.

The ECI, who will be the PI of the application, must be in the early-career stage. This award provides the ECI with funding, networking and collaborative opportunities, as well as the 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 ECI for 4 years of intensive research under the guidance of a Designated Mentor experienced in ovarian cancer research. Although the OCA will serve as a conduit to share knowledge and research experience among all Academy members, the ECI and Designated Mentor will be responsible for developing the ECI's career development plan and for designing and executing the proposed research. *The ECI must clearly articulate their commitment to a career as an ovarian cancer researcher and to participating in and contributing to the growth of the OCA.*

The Designated Mentor must have a strong record of mentoring and training early-career investigators. In addition to being a Designated Mentor to an ECI, the Mentor must agree to serve as a secondary Mentor to another ECI. With the goal to expand and enrich the mentorship capabilities of the Academy, current OCA Designated Mentors can only be a Designated Mentor to one OCA-ECI; thus, current OCA Designated Mentors cannot be named as a Designated Mentor in an FY23 application unless the period of performance of the current OCA-ECI award ends no later than July 2024. In the same manner, the Dean and Assistant Dean of the Academy cannot be listed as Designated Mentors.

The ECI is required to participate in monthly webinars, and the ECI and their Designated Mentor are required to attend a DOD OCRP biennial multi-day OCA workshop and, in alternate years, a DOD OCRP OCA 1-day workshop.

Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to be derived from the ovarian cancer research field. *If cell lines or animals are to be used, a clear justification should be provided for the choice of proposed cell line(s) or animal model(s)*. <u>Clinical trials will not be supported by this award mechanism</u>. Applicants who are interested in clinical trial research should respond to the Ovarian Cancer Clinical Trial Academy – Early-Career Investigator Award (OCCTA-ECI) program announcement, a new mechanism offered by the OCRP.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 OCRP priorities.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public. Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military Families, and the American public.

Research Involving Animals: All research funded by the FY24 OCRP OCA-ECI Award involving new and ongoing research with animals must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO) and Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. *Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Application Instructions for additional information.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under $\frac{46.104(d)(4)}{1000}$ of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 OCRP OCA-ECI] Award should not exceed **\$725,000**. Refer to <u>Section II.D.5</u>, <u>Funding Restrictions</u>, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately \$2.32M to fund approximately two OCA-ECI Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

• Early-Career Investigator

• Must be within 5 years of last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent as of the full application submission deadline.

- A Statement of Eligibility is required with the submission of the full application.
- May be a research- or physician-scientist.
- May be in a non-tenure track or tenure track position.
- Must not have a concurrent career development-like award at the time of this award. Investigators may apply to both the OCA-ECI Award and OCCTA-ECI Award funding opportunities offered by the OCRP but may not accept an award from both funding opportunities.
- Must have an institutional commitment of approximately 50% protected time for ovarian cancer research and OCA activities, including participation in monthly webinars.
 - Must commit no less than 25% effort to this award for the first 2 years.
 - Individuals in a postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent at the time of full application submission **are not eligible.**

• Designated Mentor

- 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.
- May be at the same institution as the ECI.
- If not at the same institution, another Mentor ("Other Mentor," see below) at the ECI's institution must also be included in the application submission.
- Must demonstrate a commitment (at least 5% effort for mentoring and participating in OCA activities such as offsite meetings and webinars) to develop and sustain the ECI's independent career in ovarian cancer research.
- Mentoring responsibilities include mentoring the ECI (i.e., the PI of this award) and an additional ECI within the OCA.
- A current OCA Designated Mentor can only be a Designated Mentor to one OCA-ECI; thus, current OCA Designated Mentors cannot be named as a Designated Mentor in an FY23 application unless the period of performance of the current OCA-ECI Award mechanism ends no later than July 2024.
- The current OCA Dean and/or Assistant Dean cannot be listed as a Designated Mentor.
- Off-site OCA activities include annual in-person workshops and monthly web-based meetings.

• Other Mentor (if applicable)

- Must be at the same institution as the ECI (if the Designated Mentor is not from the same institution as the ECI).
- Must be an independent cancer researcher but not necessarily in ovarian cancer.
- Must have research funding (past and present).

A map of current and past ECIs and their Designated Mentors in the OCA can be seen in Appendix 2

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Refer to <u>Section II.H.2</u>, <u>Administrative Actions</u>, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (<u>https://ebrap.org</u>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (<u>https://grants.gov</u>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.



Extramural Submission: An application submitted by an <u>extramural organization</u> for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524OCRPOCAECI from Grants.gov (<u>https://grants.gov</u>). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an <u>intramural DOD organization</u> for an investigator employed by that organization. Intramural DOD organizations <u>may</u> submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524OCRPOCAECI from the anticipated submission portal eBRAP (<u>https://ebrap.org</u>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. *The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

II.D.2. Content and Form of the Application Submission

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 OCRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to <u>Section II.H.2.c</u>, <u>Withdrawal</u>, or contact the eBRAP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507.

II.D.2.a. Step 1: Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP (<u>https://eBRAP.org/</u>).

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. No change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

• **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- Describe the ECI's (PI on this award) career goals in ovarian cancer research.
- Describe the career development plan and how the Designated Mentor (and Other Mentor, if applicable) will assist the ECI in developing and sustaining their career as an independent ovarian cancer researcher.
- Briefly describe the proposed ovarian cancer research idea that will be supported by this award, as well as the ability of the ECI to conduct the research or the relevant guidance that will be obtained to accomplish the project. If applicable, describe how research in ovarian cancer is/has been limited by either minimal or lack of resources and how this will be resolved. **Clinical trials are not allowed.** If cell lines or animals are to be used, *justify why the proposed cell line(s) or animal model(s) were chosen.*
- Describe the ECI's motivation and commitment to participating in the OCA.
- Summarize how the proposed research and participation in the OCA 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 *must be uploaded as individual files* and are limited to the following:
 - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - Key Personnel Biographical Sketches (five-page limit per individual): *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
 - ECI Biographical Sketch
 - ECI Previous/Current/Pending Support
 - Designated Mentor Biographical Sketch
 - Designated Mentor Previous/Current/Pending Support
 - Other Mentor Biographical Sketch, if applicable

- **Statement of Eligibility (one-page limit):** Use the suggested OCA-ECI Award Eligibility Statement Template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.
- Additional Information (one-page limit): One page for additional information can be used, at the PI's discretion, to provide supporting data or rationale or justification for the proposed research. If no additional information will be submitted, include a page with the statement, "No additional information."

II.D.2.a.ii. Pre-Application Screening Criteria

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

- The ECI (PI on this award) meets eligibility requirements at the time of full application submission.
- The ECI's (PI's) career goals in ovarian cancer research.
- How well the proposed research plan and participation planning the OCA will help the ECI in promoting an independent, sustainable career in ovarian cancer research.
- How the Designated Mentor and Other Mentor, if applicable, will assist the ECI.
- The ECI's motivation and commitment to participating in the OCA.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in <u>Section I, Overview of the Funding</u> <u>Opportunity</u>. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full 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.

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

II.D.2.b. Step 2: Full Application Submission

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<u>https://grants.gov/</u>) for extramural organizations or through eBRAP (<u>https://ebrap.org/</u>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations *must* be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components

Each application submission must include the completed full application package for this program announcement. See <u>Section II.H.3</u> of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form (*Extramural Submissions Only*): Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

• Attachment 1: Project Narrative (12-page limit): Upload as

"ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and nontext elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application. Describe the proposed project in detail using the outline below.

- ECI's Career Goals (one-page limit recommended): Discuss the ECI's record of accomplishments, demonstrating the potential for becoming an independent investigator in ovarian cancer research. Describe the ECI's career goals and plans in ovarian cancer research and how the proposed research and career development experience will promote an independent, sustainable career.
- Research Project and Feasibility (eight-page limit recommended): Concisely explain the project's specific aims to be funded by this application. Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.
 - Describe how data will be collected, handled, and analyzed in a manner that is consistent with the study objectives.
 - Describe the statistical plan including a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
 - If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen.
 - If human subjects, human biological samples, or datasets will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples.
 - If applicable, describe the strategy for the inclusion of minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of racial, and ethnic group, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement.
- Integration of Career Development and Research (one- to one-and-a-half-pagelimit recommended): Describe how the individualized career development plan and research project are integrated and how they will contribute to preparing the ECI for an independent, sustainable career in ovarian cancer research.
- Commitment to the OCA (one- to one-and-a-half-page limit recommended): Describe why participation in the OCA is important in developing the ECI's career. Describe the ECI's motivation and commitment to participating in the OCA, to include networking and collaborating with other ECI/Designated Mentor pairs (and, if applicable, an Other Mentor) and the OCA Leadership.

• Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf". Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- 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 whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (*if applicable*): Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."
 - **Intellectual and Material Property Plan** (*if applicable*): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Commercialization Strategy** (*if applicable*): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- DOD Data Management Plan (two-page limit is recommended): Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. Do not duplicate the Data and Research Resources Sharing Plan. Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- Data and Research Resources Sharing Plan: Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to the CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and resources publicly available.
- Use of DOD Resources (*if applicable*): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

Use of U.S. Department of Veterans Affairs (VA) Resources (*if applicable***):** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf". The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly*. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important. Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- Career Development Sustainment Plan

- Summarize how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the ECI's independent career at the forefront of ovarian cancer research.
- Describe how the proposed research project will allow the PI to make valuable contributions to ovarian cancer.
- Research Plan
 - **Background:** Present the scientific rationale behind the proposed research project.
 - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
 - **Specific Aims:** State the specific aims of the study.
 - **Study Design:** Describe the study design, including appropriate controls.
 - **Impact:** Describe how the proposed research will make an important contribution toward the goal of eliminating ovarian cancer. Describe the potential impact of the proposed research on the health and well-being of Service Members, Veterans, their Family members, and all women impacted by this disease.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf". The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly*. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. *Do not duplicate the technical abstract*.

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

- Describe the hypothesis 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 do the research and career development plans support the PI in attaining these goals?
- Describe how the PI will participate in and contribute to the growth of the OCA.
- 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 are the likely contributions of this study to advancing our knowledge of ovarian cancer?
- What is the potential impact of the proposed research on the health and well-being of Service Members, Veterans, their Family members, and all women impacted by this disease?
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf". Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.
- For the OCA-ECI Award, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

• Attachment 6: Career Development and Sustainment Plan (two-page limit): Upload as "CareerSustain.pdf".

 Describe the individualized career and professional development plan, which may include workshops, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Explain how this development plan will enable the ECI to obtain independent ovarian cancer research funding and publish in peerreviewed journals.

- Discuss how the Designated Mentor and Other Mentor, if applicable, will assist the ECI in not only developing, but also sustaining, a career as an independent ovarian cancer researcher. Explain how the Career Development and Sustainment Plan is supported by the environment; this should include a description of resources available to the ECI at their institution, and, if different, at the Designated Mentor's institution.
- Outline how the ECI and Designated Mentor (and Other Mentor, if applicable) will evaluate the ECI's progress of achieving and, more importantly, sustaining a productive and independent career in ovarian cancer research.

• Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf".

Explain how the proposed research and Career Development and Sustainment Plan will facilitate professional development and sustain the ECI's independent career at the forefront of ovarian cancer research. Describe how the proposed research will make a contribution toward the OCRP mission and will impact ovarian cancer research and/or patient care/or survivorship. The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

• Attachment 8: Designated Mentor's Letter (three-page limit): Upload as "MentorLetter.pdf".

- The Designated Mentor's letter should describe the ECI's background and potential to become an independent ovarian cancer researcher. Explain how this award will enhance the ECI'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 ECIs. Specify the commitment of the Designated Mentor (at least 5% effort) and their staff to the ECI's professional development and career sustainment. Describe the specific resources that will facilitate success for the ECI.
- Describe why the Designated Mentor will be a "great" fit in the OCA irrespective of their accomplishments as a researcher and mentor to other ECIs. Describe the Designated Mentor's motivation and commitment to participating in the OCA with the other ECI/Designated Mentor pairs and the Academy Leadership. Describe the Designated Mentor's commitment and time to serve as a secondary mentor to another ECI in the OCA.

• Attachment 9: Other Mentor's Letter for the OCA-ECI Award application, if applicable (two-page limit): Upload as "OtherMentor.pdf".

- The Other Mentor's letter should describe the ECI's background and potential to become an independent ovarian cancer researcher. Explain how this award will enhance the ECI's capabilities to sustain a career in ovarian cancer research.

 Describe the Other Mentor's background and experience in research, success in acquiring funding, and record of mentoring and training ECIs. Describe the specific resources that will facilitate success for the ECI.

- Describe the Other Mentor's motivation and commitment to participating in the OCA with the other ECI/Designated Mentor pairs and the Academy Leadership.

• Attachment 10: Statement of Eligibility (one-page limit): Upload as "Eligible.pdf".

Use the suggested OCA-ECI Award Eligibility Statement Template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements are met at the application submission deadline.

• Attachment 11: Inclusion of Minorities Inclusion Enrollment Report (Attachment 11 is only applicable and required for applications proposing clinical research studies): Upload as "IWAM.pdf".

Describe the strategy for the inclusion of minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of race and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- Attachment 12: Representations (*Extramural Submissions Only*): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (<u>https://ebrap.org/eBRAP/</u> <u>public/Program.htm</u>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 13: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as "IGBudget.pdf". If an <u>intramural DOD organization</u> will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (<u>https://ebrap.org/eBRAP/public/Program.htm</u>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

- (d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
 - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf".
 - **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- (e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
 - Budget Justification (no page limit): For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (*if applicable, Extramural Submissions Only*): Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
 - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
 - Intramural DOD Subaward: Complete a separate "<u>Suggested</u> <u>Intragovernmental/Intramural Budget Form</u>" for each intramural DOD subaward and upload as a single document titled "IGBudget.pdf" to Grants.gov as Attachment 13.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP

does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.* Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application period. The full application cannot be modified once the application verification period.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (<u>https://www.sam.gov/content/home</u>) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

The maximum period of performance is 4 years.

The application's direct costs budgeted for the entire period of performance should not exceed **\$725,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs must be requested for:

• Annual OCA workshop: Travel costs for the ECI and Designated Mentor (and Other Mentor, if applicable) to attend a DOD OCRP 1-day OCA Workshop with the Academy Leadership and other Academy members every other year.

• Biennial OCA workshop: Travel costs for the ECI and Designated Mentor (and Other Mentor, if applicable) to attend a biennial DOD OCRP multi-day OCA Workshop with the OCRP staff, Academy Leadership, and other Academy members.

May be requested for (not all-inclusive):

- Funding for the Designated Mentor(s)'s salary support is encouraged up to the equivalent of 2 calendar months per year.
- If applicable, funding for Other Mentor must be justified.
- Travel costs between collaborating organizations
- Travel in support of multidisciplinary collaborations
- Costs associated with participating in the virtual OCA (e.g., hardware and/or software for the audio- or video-teleconferencing or web-based communications)
- Costs for one investigator to travel to two scientific/technical meetings per year, in addition to the required OCA meeting described above. The intent of travel costs to scientific/ technical meetings is to present project information or disseminate project results and/or attend workshops as designated in the Career Development and Sustainment Plan of the OCRP OCA-ECI Award.

Must not be requested for:

- Clinical trial costs
- Tuition

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are of equal importance:

Early-Career Investigator

• The degree to which the ECI's career goals are consistent with a commitment to pursuing and sustaining a career as an ovarian cancer researcher.

- The extent to which the ECI is motivated and committed to participating in the OCA with the other ECI/Designated Mentor pairs and the Academy Leadership.
- How well the Designated Mentor's letter (and, if applicable, the Other Mentor's letter) supports the ECI's potential for a productive, sustainable, and independent career in ovarian cancer research.
- The extent to which the ECI's record of accomplishments (awards, honors, first author publications, publications in high-impact journals, presentations/speaking engagements, committees, etc.) demonstrates their potential for becoming an independent investigator in ovarian cancer research.

Research Project and Feasibility

- The extent to which 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, experimental design, methods, and analyses are developed and support completion of the aims.
- To what extent the power analysis demonstrates that the sample size is appropriate to meet the objectives of the study, and how well the statistical plan and analyses are developed and integrated into the project.
- If applicable, whether the strategy for the inclusion of minorities and distribution of proposed enrollment are appropriate for the proposed research.
- How well potential problems are identified and alternative approaches are addressed.

Career Development and Sustainment Plan

- How well the application outlines an individualized Career Development and Sustainment Plan for the ECI that is consistent with the OCA and the ECI's research goals.
- How well the individualized Career Development and Sustainment Plan will contribute to the overall professional development of the ECI and prepare the ECI for an independent and sustainable career in ovarian cancer research.
- How well the Career Development and Sustainment Plan is supported by the environment at the ECI's institution, and, if different, at the Designated Mentor's institution.
- How thorough the plans are for monitoring and evaluating the ECI's progress in becoming an independent investigator in ovarian cancer research.

Designated Mentor (and, if applicable, Other Mentor)

- The extent to which the Designated Mentor's (and, if applicable, the Other Mentor's) background, research experience, and funding history in ovarian cancer will be supportive of the ECI's career and professional development and transition to independence.
- How well the Designated Mentor's track record in preparing ECIs for careers in ovarian cancer research indicates the potential for successful mentorship and development of the ECI as an independent investigator.
- How well the Designated Mentor describes their motivation and commitment to participating in the OCA, and why they will be a "great" fit in the Academy irrespective of their accomplishments as a researcher and mentor to other ECIs.

Impact

- To what degree the anticipated results from the proposed research will make a contribution to the OCRP mission and will impact ovarian cancer research and/or patient care/or survivorship.
- How impactful are the proposed research project, Career Development and Sustainment Plan, and commitment plan to facilitate professional growth of the ECI and bring the PI to the forefront of ovarian cancer research.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

• Resources and Environment

- The extent to which the proposed research project and career development of the ECI are supported by the availability of facilities, equipment, staff, interaction with research colleagues, and other resources.
- How well the commitment from the institution (of at least 50% protected time) supports the career development of the ECI including time for research and participation in OCA activities such as monthly webinars.
- If applicable, the degree to which the intellectual and material property plan is appropriate.

• Budget

- Whether the direct costs exceed the allowable direct costs, as published in the program announcement.
- Whether the budget is appropriate for the proposed research.

• Application Presentation

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

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 OCRP, as evidenced by the following:
 - o Adherence to the intent of the award mechanism
 - Program portfolio balance and composition
 - Relative impact on ovarian cancer

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding*. *Funding recommendations depend on various factors as described in <u>Section II.E.1.b, Programmatic Review</u>.* Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the meritbased selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval 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 panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the OCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to *intragovernmental and intramural DOD organizations* will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization

Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> <u>Terms and Conditions</u>: <u>Addendum to the DoD R&D Terms and Conditions</u> for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC OHARO prior to implementation. This administrative review requirement is in addition to the

local IACUC, Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report.

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template, "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (<u>https://ebrap.org/eBRAP/public/Program.htm</u>) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

PHS Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*): Enrollment reporting on the basis of race and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (<u>https://ebrap.org/eBRAP/public/Program.htm</u>) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission:

Phone: 301-682-5507

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

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

Phone: 800-518-4726; International 1-606-545-5035

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

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of pre-applications or full applications, the following administrative actions may occur.

II.H.2.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 full application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Pre-application was not submitted.
- Submission of an application for which a letter of invitation was not received.
- The application proposes a clinical trial.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 OCRP Programmatic Panel 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 documentation, including letters of support/recommendation. *A list of the FY24 OCRP Programmatic Panel members can be found at https://cdmrp.health.mil/OCRP/panels/panels24*.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The Designated Mentor and/or Other Mentor do not meet the eligibility criteria.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance (Extramural submissions only)	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	
Statement of Work – Attachment 5, upload as "SOW.pdf"	
Career Development and Sustainment Plan – Attachment 6, upload as	
"CareerSustain.pdf"	
Impact Statement – Attachment 7, upload as "Impact.pdf"	
Designated Mentor's Letter – Attachment 8, upload as "MentorLetter.pdf"	
Other Mentor's Letter (<i>if applicable</i>) – Attachment 9, upload as "OtherMentor.pdf"	
Statement of Eligibility – Attachment 10, upload as "Eligible.pdf"	
Inclusion of Minorities Inclusion Enrollment Report – Attachment 11, upload as "IWAM.pdf"	
Representations (<i>Extramural submissions only</i>) – Attachment 12, upload as "RequiredReps.pdf"	
Suggested Intragovernmental/Intramural Budget Form (<i>if applicable</i>) – Attachment 13, upload as "IGBudget.pdf"	
Research & Related Personal Data	
Research & Related Senior/Key Person Profile (Expanded)	
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	
Research & Related Budget (<i>Extramural submissions only</i>) Include budget justification	
Budget (Intramural submissions only) Include budget justification	
Project/Performance Site Location(s) Form	
Research & Related Subaward Budget Attachment(s) Form (if applicable)	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ECI	Early-Career Investigator
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
Μ	Million
MIPR	Military Interdepartmental Purchase Request
OCA	Ovarian Cancer Academy
OCRP	Ovarian Cancer Research Program
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

APPENDIX 2: MAP OF CURRENT AND PAST OCA-ECI'S AND DESIGNATED MENTORS

