

Program Announcement for the Department of Defense Defense Health Program

Ovarian Cancer Research Program Investigator-Initiated Research Award

Funding Opportunity Number: HT942525OCRPIIRA

Pre-Application Due: June 12, 2025

Application Due: September 11, 2025

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Before You Begin

- Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission. User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- Read the funding opportunity announcement in the order it is written before beginning to prepare application materials. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.

Who to Contact for Support

eBRAP Help Desk

301-682-5507 help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

800-518-4726 International: 1-606-545-5035 support@grants.gov

> Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

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1. Basic Information About the Funding Opportunity

Summary: The Ovarian Cancer Investigator-Initiated Research Award (OCRP) Investigator-Initiated Research Award is intended to support high-impact research that addresses a critical need and has the potential to make an important contribution to ovarian cancer or patient/survivor care.

Distinctive Features: Application must contain strong research plan with sound scientific rational and logical reasoning. Preliminary data are required. Research projects may focus on any phase of research, from basic laboratory research through translational research, excluding clinical trials.

Partnering Principal Investigator (PI) Option: The Partnering PI Option is structured so that two investigators, each of whom will be designated as a PI, will work synergistically on a single project. The results of this partnering project should significantly advance the research beyond what would be possible through individual efforts.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$8.05M to fund approximately seven Investigator-Initiated Research Award applications with total cost caps of \$1.05M for a single PI or combined total cost caps of \$1.4M for Partnering PIs. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 12, 2025
- Invitation to Submit an Application: July 17, 2025
- Application Submission Deadline: 11:59 p.m. ET, September 11, 2025
- End of Application Verification Period: 5:00 p.m. ET, September 16, 2025
- Peer Review: November 2025
- Programmatic Review: January 2026

Announcement Type: Initial

Funding Opportunity Number: HT942525OCRPIIRA

Assistance Listing Number: 12.420

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2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply, *including foreign and domestic organizations, for-profit and non-profit organizations, and public or private entities*.

Extramural Organization: An eligible non-Department of Defense (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.

2.1.2. Principal Investigator

Pls must be at or above the level of Assistant Professor (or equivalent).

Partnering PI Option: Up to two investigators may collaborate on a single application, each of whom will be recognized as a PI and receive a separate award.

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

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

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3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the OCRP. Congress initiated the OCRP in FY07 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the OCRP from FY97 through FY24 totaled \$541.45 million (M). The FY25 appropriation is \$15M.

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

3.1. Award History

The OCRP Investigator-Initiated Research Award mechanism was first offered in FY14. Since then, 992 Investigator-Initiated Research Award applications were received, and 144 were recommended for funding.

3.2. Intent of the Investigator-Initiated Research Award

The OCRP Investigator-Initiated Research Award is intended to support high-impact research that addresses a critical need and has the potential to make an important contribution to ovarian cancer or patient/survivor care. Research projects may focus on any phase of research, from basic laboratory research through translational research, excluding clinical trials. The application must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Applications must include preliminary data that are relevant to ovarian cancer and support the proposed research project. These data may be unpublished or from the published literature.

Clinical trials are not supported under this award mechanism.

3.2.1. Areas of Emphasis for the IIRA

To meet the intent of the funding opportunity, applications for the FY25 OCRP Investigator-Initiated Research Award (IIRA) must address a critical component of at least one of the Areas of Emphasis listed below:

- Understand the basic biology and etiology of ovarian cancer initiation, progression, metastasis, recurrence, genetics, and other critical events.
- Develop novel therapeutic strategies for treatment.
- Investigate innovative approaches for ovarian cancer prevention.
- Identify and develop new strategies for screening, early-stage detection, accurate diagnosis, and prognosis.
- Identify and implement strategies to improve survivorship and quality of life.
- Improve precision medicine.

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3.2.2. Key Elements for the IIRA

The IIRA includes an option for more than one PI. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section 5.3, Submission Instructions.

The anticipated total costs budgeted for the entire period of performance for an FY25 OCRP Investigator Initiated Research Award should not exceed \$1.05M with a single PI or \$1.4M with a Partnering PI. Refer to Section 3.5, Funding Details, for detailed funding information.

Awards supported with FY25 funds will be made no later than September 30, 2026.

3.2.3. Other Important Considerations for the IIRA

The proposed research must be relevant to Service Members, Veterans, military beneficiaries, and/or the American public. Applications from investigators within the DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families.

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. An **intervention** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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:

- (1) 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.

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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 §46.104(d)(4) of the Common Rule.

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).

Research Involving Animals: All research funded by the FY25 OCRP IIRA 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.

3.3. CDMRP-wide Encouragement(s)

The following encouragement(s) are broadly applicable across many CDMRP programs, including the OCRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

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, 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 FY25 OCRP priorities.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

3.4. Funding Instrument

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

3.5. Funding Details

Period of Performance: The maximum period of performance is **4** years. **The period of performance is not to exceed 4 years.**

No Partnering PI Option:

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **\$1.05M**. 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.

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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.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Partnering PI Option

Cost Cap: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **\$1.4M**. 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.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Any application that requests the higher level of funding and that does not include a Partnering PI will have its budget reduced as appropriate.

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.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the OCRP IIRA.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Tuition.
- Clinical trial costs.

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4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (<u>eBRAP</u>) and a *full application* submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

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 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:

Background/Readiness

- State the ideas and scientific rationale on which the proposed research project is based. Cite relevant literature. If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen.
- Clearly state the stage of study proposed (e.g., development, animal validation, human anatomical substances, translational human studies) and demonstrate that there is sufficient scientific evidence to support moving into the stage of proposed research.
- Briefly state the qualifications of the PI(s) and key personnel to perform the described research project.

Hypothesis, Specific Aims, and Approach

 Concisely state the project's hypothesis and specific aims and describe the scientific approach. Include appropriate controls and demonstrate that the work is appropriately powered.

Areas of Emphasis Relevance

 Explain how the proposed research will lead to promising outcomes for one or more of the <u>FY25 OCRP Areas of Emphasis</u> in Section 3.2.1

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Impact

- Describe the potential immediate or long-range outcome(s) of the proposed research and their impact on ovarian cancer or patient care/survivorship.
- Explain why the proposed research is critical to the field.
- **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: 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.

4.3. Step 2: Full Application Components

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

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The application submission process for Partnering PI uses an <u>abbreviated full application</u> package.

4.3.1. Full Application Components for the PI or Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

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

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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 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 that expands the Project Narrative and could confer an unfair

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competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- Background/Readiness: Present the ideas and scientific rationale for the proposed research project. Clearly demonstrate that there is sufficient scientific evidence to support moving into the proposed stage of research. *Include preliminary data that are relevant to ovarian cancer and the proposed project.* Cite relevant literature.
- Hypothesis: State the hypothesis to be tested.
- Specific Aims: Concisely explain the project's specific aims to be funded by this application. The specific aims should be aligned with the specific aims/tasks outlined in the Statement of Work (SOW). If this project is part of a larger study, present only tasks that this OCRP award would fund.
- Research Strategy and Feasibility: 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. *This award may not be used to conduct clinical trials*. Please see the <u>definition of clinical research</u> in Section 3.2.3., Award Information. If applicable, describe the strategy for the inclusion of diverse populations 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. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity should be provided as part of Attachment 7.

It is not expected that every study will include all racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race are exempt from this requirement.

 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.

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- 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 Support: Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the U.S. Department of Veterans Affairs (VA) Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- 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.
- Data and Research Resources Sharing Plan: Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities. Include the name of the repository(ies) where scientific data and resources arising from the proposed study 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 CDMRP's Policy

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on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

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.

- Background: Present the scientific rationale behind the proposed research project.
- Area of Emphasis: State the <u>FY25 OCRP Area(s)</u> of <u>Emphasis</u> that will be addressed.
- 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 is relevant to the vision and mission of the OCRP. Outline the potential short-term or long-term impact of the proposed research on ovarian cancer. Describe the 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 of scientific jargon, acronyms, and abbreviations.

- Summarize the objectives and rationale for the proposed research.
- Describe the central problem addressed in the proposed research and how it would advance the field of ovarian cancer research and/or patient/survivor care.
- Which FY25 OCRP Area(s) of Emphasis is addressed?
- What are the potential clinical applications, benefits, and risks (potential long-term outcomes)? If the research is too basic for clinical applicability, describe the shortterm outcomes.
- What is the 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 (three-page limit): Upload as "SOW.pdf". Refer to eBRAP for the "Suggested SOW Format".

For the Investigator-Initiated Research Award, refer to either the <u>"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work"</u> or <u>"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work"</u>

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<u>Generic Statement of Work</u>", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.

Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.

- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".
 - State explicitly how the proposed work addresses critical component of at least one of the FY25 OCRP Areas of Emphasis. Describe how the research addresses a critical need in ovarian cancer and has the potential to make an important contribution to the ovarian cancer research field and/or patient care/survivorship. Describe the anticipated outcomes from the proposed research, either short-term or long-term, and how they will make an important contribution to the ovarian cancer research field or patient care/survivorship. Explain how the proposed research will have an impact on the health and well-being of Service Members, Veterans, and their Family Members.
- Attachment 7: Enrollment Report (Attachment 7 is only applicable and required for applications proposing clinical research studies): Upload as "Enrollment.pdf". Describe the strategy for the inclusion of diverse populations 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 8: Partnership Statement (one-page limit) (Attachment 8 is only applicable and required for applications submitted under the Partnering PI Option): Upload as "Partnership.pdf". Describe the partnership and combined expertise and different strengths of the Initiating and Partnering PIs that are critical for the research strategy and completion of the SOW. Describe how the combined effort will be synergistic and produce an outcome greater than what could be achieved by independent efforts. Outline the contribution and time commitment of each partner and how each will have equal intellectual input on the design, conduct, and analysis of the project. Describe how the PIs will manage the collaboration and workflow to optimize research efforts.
- Attachment 9: Animal Research Plan (2-page limit): Upload as "AnimalResPlan.pdf". (Attachment 9 is only applicable and required for applications proposing animal studies.) If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting In Vivo Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the IACUC. The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

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- Briefly describe the research objective(s) of the animal study. Explain how and why
 the animal species, strain, and model(s) being used can address the scientific
 objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Attachment 10: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 11: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.
- (c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
 - Biographical Sketch: Upload as "Biosketch_LastName.pdf".
 - The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.
 - Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).
 - Current/Pending Support: Upload as "Support LastName.pdf".

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Current and pending (other) support information are used to assess the capacity or any <u>conflicts of commitment</u> that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

Budget Justification (no page limit): For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.

Initiating and Partnering Pls must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating Pl should not include budget information for Partnering Pl(s) even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.

- **(f) Project/Performance Site Location(s) Form:** For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.
 - Extramural Subaward: Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.

Intramural DOD Subaward: Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

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

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(b) Attachments:

Attachment 5: Statement of Work (Three-page limit): Upload as "SOW.pdf". Each
 PI must submit an identical copy of a jointly created SOW.

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- Attachment 10: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf".
- Attachment 11: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".
- (c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
- (e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).
 - o Budget Justification (no page limit): Upload as "BudgetJustification.pdf".
 - Initiating and Partnering PI must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.
- **(f) Project/Performance Site Location(s) Form:** For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions Only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.
 - Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov.
 - o **Intramural DOD Subaward:** Complete the "<u>Suggested Intragovernmental/Intramural Budget Form</u>" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov.

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instruction 3200.12 will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

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5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525OCRPIIRA from <u>Grants.gov</u> or <u>eBRAP</u>, depending on which submission portal will be used.

5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), <u>SAM.gov</u>, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

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

Step1: Submit Pre-Application Preproposal Submitted Through eBRAP Receive Invitation to Submit Full Application Step 2: Submit Full Application Grants.gov Extramural Organizations Verify Application Content in eBRAP

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5.3.1. Pre-Application Submission

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI (if exercising the Partnering PI Option).

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 preapplication 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. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI[(s)] will be notified of the pre-application submission via an email from eBRAP. The Partnering PI[(s)] must follow the link in the notification email to associate the partnering pre-application with their eBRAP account and confirm their organization and Business Official information. If not previously registered, the Partnering PI must register in eBRAP.

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
Single PI	IIRA – Investigator-Initiated Research Award
Partnering PI	IIRA-PPIO – Investigator-Initiated Research Award – Partnering PI Option

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application

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Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. 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 the 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 through the appropriate portal 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 verification period. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in 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.*

All submission dates and times are indicated in <u>Section 1</u>, <u>Basic Information</u> above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, 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.

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.

Members of the FY25 OCRP Programmatic Panel should not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members *may* provide letters to confirm PI eligibility and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). A list of the FY25 OCRP Programmatic Panel members can be found on the CDMRP website.

Additional restrictions and associated administrative responses are outlined in <u>Section 9.2</u>, <u>Administrative Actions</u>.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

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

- Background/Readiness: How well the described research demonstrates scientific rationale
 for ovarian cancer research and provides sufficient evidence that the research is ready to
 move into the stage of proposed research. How appropriate the personnel's background and
 expertise are to accomplishing the proposed research.
- **Hypothesis**, **Specific Aims**, **and Approach**: How well a clear hypothesis is stated and supported through scientific rationale and referenced literature. How well the specific aims and approach will address the hypothesis.
- Areas of Emphasis of Relevance: Whether the proposed project addresses at least one of the <u>FY25 OCRP Areas of Emphasis</u>. To what degree the proposed research may lead to promising outcomes for one or more of the selected FY25 OCRP Areas of Emphasis.
- **Impact:** To what extent the potential immediate or long-range outcome(s) of the proposed research, if successful, will impact ovarian cancer or patient care/survivorship. To what extent the proposed research is critical to the field.

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6.2.2. Peer Review Criteria

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria** of which Research Strategy and Feasibility is the most important and the remaining criteria listed are of equal importance:

Research Strategy and Feasibility

- How well the preliminary data and scientific rationale support the proposed research project and demonstrate sufficient evidence to support moving into the stage of the proposed research project.
- How well the hypothesis, aims, experimental design, and methods are developed and integrated into the project.
- 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.
- To what extent the data will be handled, collected, and analyzed in a manner that is consistent with the study aims.
- If applicable, whether the strategy for the inclusion of diverse populations and distribution of proposed enrollment are appropriate for the proposed research.
- How well potential problems are identified and alternative approaches are addressed.

Impact

- Whether the application stated explicitly how the proposed work addresses a critical component in at least one of the FY25 OCRP Areas of Emphasis.
- How well the proposed research addresses a critical need in the field of ovarian cancer research and/or patient care/survivorship.
- To what degree the anticipated outcomes, either short- or long-term, will make an important contribution to the ovarian cancer research field or patient/survivor care.

Personnel

- To what extent the background and expertise of the PI(s) and key personnel will contribute to the success of the proposed project.
- To what degree the levels of effort by the PI(s) and key personnel will ensure the success of the proposed work.
- **Partnering PI Option:** How the partners' combined expertise will better address the research question.

For applications submitted under the Partnering PI Option:

Partnership

- How well the research project is supported by the nature of the collaboration.
- To what extent the proposed partnership is synergistic and will advance research beyond what would be possible through individual efforts.

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**:

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Budget

• Whether the budget is appropriate for the proposed research.

Environment

- To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.

Application Presentation

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

6.2.3. 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 FY25 OCRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity
 - Program portfolio balance
 - Relative impact on ovarian cancer

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating 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 Section 1, Basic Information about the Funding Opportunity. No feedback (e.g., a critique of the preapplication'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.

6.3.2. Full Application

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 6.2.3</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found on the <u>CDMRP website</u>.*

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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.

6.4. Risk, 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.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the Office of the Under Secretary of Defense for Research and Engineering Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

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7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within six weeks after programmatic review. 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 application receipt 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 additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

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8. Post-Award Requirements

8.1. 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> Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

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.

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 (IRB), or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. 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, using the template available on eBRAP, must be submitted with the final progress report.

PHS Inclusion Enrollment Reporting (*Required for research proposing clinical research and/or clinical trials*): Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on 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).

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8.3. Additional Requirements

An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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 H, for general information on organization or PI changes.

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9. Other Information

9.1. 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 CD25_01c. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. 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 is missing.
- Budget is missing.
- Pre-application was not submitted.
- Submission of an application for which a letter of invitation was not issued.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY25 OCRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the preapplication or application processes.
- Applications that include names of personnel from either of the CDMRP peer or
 programmatic review companies for which conflicts cannot be adequately mitigated. For
 FY25, the identities of the peer review contractor and the programmatic review contractor
 may be found on the <u>CDMRP Website</u>.
- 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- 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.
- 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 invited application proposes a different research project than that described in the preapplication.
- A clinical trial is proposed.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

9.2.4. 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.

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance (Grants.gov submissions only)		
Summary (Tab 1) and Application Contacts (Tab 2) (eBRAP submissions only)		
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"		
<u>Supporting Documentation</u> – 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"		
Impact Statement - Attachment 6, upload as "Impact.pdf"		
Enrollment Report (if applicable) – Attachment 7, upload as "Enrollment.pdf"		
Partnership Statement (for Partnering PI Option applications only) – Attachment 8, upload as "Partnership.pdf"		
Animal Research Plan (if applicable) – Attachment 9, upload as "AnimalResPlan.pdf".		
Representations (Grants.gov submissions only) – Attachment 10, upload as "RequiredReps.pdf"		
<u>Suggested Intragovernmental Budget Form</u> (if applicable) – Attachment 11, upload as "IGBudget.pdf"		
Research & Related Personal Data		
Research & Related Senior/Key Person Profile (Expanded)		
Attach <u>Biographical Sketch</u> for PI and Senior/Key Persons (Biosketch_LastName.pdf)		
Attach <u>Current and pending (other) support</u> for PI and Senior/Key Persons (Support_LastName.pdf)		
Budget Include budget justification		
Project/Performance Site Location(s) Form		
Research & Related Subaward Budget Attachment(s) Form (if applicable)		

Basic Information | Eligibility | Program Description | Application Contents and Format | Submission Requirements Application Review Information | Federal Award Notices | Post-Award Requirements | Other Information

Appendix 2. Acronym List

ACURO Animal Care and Use Review Office

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations

DOD Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

EC Ethics Committee
ET Eastern Time

FAD Funding Authorization Document

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

IIRA Investigator-Initiated Research Award

IRB Institutional Review Board

M Million

MIPR Military Interdepartmental Purchase Request

NIH National Institutes of Health

NSF U.S. National Science Foundation

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

RPPR Research Performance Progress Report

SAM System for Award Management

SciENcv Science Experts Network Curriculum Vitae

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