Program Announcement for the Department of Defense
Defense Health Program

Ovarian Cancer Research Program

Ovarian Cancer Clinical Trial Academy – Early-Career Investigator Award

Funding Opportunity Number: HT942525OCRPOCCTAECI

Pre-Application Due: June 12, 2025

Application Due: September 11, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_01.

Content

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.

1. Basic Information About the Funding Opportunity

Summary: The Ovarian Cancer Clinical Trial Academy (OCCTA) supports the next generation of Early-Career Investigators (ECIs) in clinical trial research to produce effective treatments and cures for ovarian cancer. The OCCTA, through its Leadership, provides for professional and leadership development of the ECIs to include skills and competencies needed to execute clinical trials, providing intensive mentoring, national networking, collaborations, and a peer group for junior clinical trialists. The OCCTA will bring together established investigators (the Academy Dean and Assistant Dean), established Career Guides (mentors), and a group of ECIs/Scholars to conduct successful, highly productive clinical trials in ovarian cancer.

Distinctive Features: Research funded under this FY25 funding opportunity will support translational research and small-scale, early-phase clinical trials in ovarian cancer. Preliminary data are required, however, these data do not necessarily need to be derived from the ovarian cancer research field. ECI must be within 12 years of last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent at the time of full application submission deadline. Must commit no less than 25% effort to this award and/or OCCTA activities for the first 2 years. The Designated Mentor must be a clinical trialist with a strong record of mentoring and training early-career investigators.

Beyond research, OCCTA ECIs will be expected to participate in monthly webinars and annual workshops and to communicate and collaborate with other members of the OCCTA (other ECIs, Mentors, Dean, Assistant Dean) as well as with the advocacy community.

The ECI must clearly articulate their commitment to a career as an ovarian cancer clinical trialist and to participating in and contributing to the growth of the OCCTA.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $1.4M to fund approximately one Ovarian Cancer Clinical Trial Award – Early-Career Investigator Award applications with total cost caps of $1.4 million (M). 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: HT942525OCRPOCCTA-ECI

Assistance Listing Number: 12.420

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

- **Early-Career Investigator**
  - Must be within 12 years of last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent at the time of full application submission deadline.
    - A Statement of Eligibility is required with the submission of the full application.
    - For industry, investigators at or above an independent scientist level may be named by the company as the PI on the application, provided they meet the criteria listed above.
  - Must commit no less than 25% effort to this award and/or OCCTA activities 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 clinical trialist and have a balanced portfolio of successful clinical trial experience.
  - Must have an active clinical trial at the time of application.
  - 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 have experience in ovarian cancer research if the ECI's experience is not in ovarian cancer research.
  - Must demonstrate a commitment to develop and sustain the ECI's independent career in ovarian cancer research (it is recommended that the Designated Mentor demonstrate a 5% effort for mentoring and participating in OCCTA activities such as offsite meetings and webinars). Mentor responsibilities include mentoring the ECI (i.e., the PI of this award) and an additional ECI within the OCCTA. Offsite OCCTA activities include annual in-person workshops and monthly web-based meetings.

  - A current OCA Designated Mentor can only be a Designated Mentor to one Ovarian Cancer Academy – Early-Career Investigator at a time; thus, current OCA Designated Mentors cannot be named as a Designated Mentor in an FY25 application unless the period of performance of the current Ovarian Cancer Academy – Early-Career Investigator Award mechanism ends no later than July 2026. The current OCCTA Dean and/or Assistant Dean cannot be listed as a Designated Mentor.

- **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 clinical trialist or an independent researcher in ovarian cancer. The Designated Mentor or Other Mentor must have experience in ovarian cancer research if the ECI's experience is not in ovarian cancer research.
  - Must have research funding (past and present).

Individuals affiliated with an eligible organization are eligible to be named as Principal Investigator (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.

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 Ovarian Cancer Research Program (OCRP). 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 FY24 totaled $541.45M. 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 health and well-being of Service Members, Veterans, their Family members, and all women impacted by this disease.

3.1. Award History

The OCRP Ovarian Cancer Clinical Trial Award – Early-Career Investigator Award mechanism was first offered in FY24. Since then, four Ovarian Cancer Clinical Trial Award – Early-Career Investigator Award applications were received, and two were recommended for funding.

3.2. Intent of the Ovarian Cancer Clinical Trial Award – Early-Career Investigator

The intent of the OCCTA is to enhance knowledge within next generation of ECIs in clinical trial research and to produce effective treatments and cures for ovarian cancer. The OCCTA enables the ECI (the investigator named as the PI on the application) to pursue funding for ovarian cancer clinical trial research under the guidance of a Designated Mentor. Because of the early-career nature of the PI, clinical trials initiated or collaborated with during the award period of performance are anticipated to be the led by the Designated Mentors. Beyond research, OCCTA ECIs will be expected to participate in monthly webinars and annual workshops and to communicate and collaborate with other members of the OCCTA (other ECIs, Mentors, the Dean and Assistant Dean), as well as with the advocacy community.

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 clinical research. This award also provides support and protected time for the ECI for 4 years of intensive research under the guidance of the Designated Mentor. Although the OCCTA will serve as a conduit to share knowledge and research experience among all OCCTA members, the ECI and Designated Mentor will be responsible for designing and executing the proposed research and for developing the ECI's career development plan.

3.2.1. Key Elements for the Ovarian Cancer Clinical Trial Award – Early-Career Investigator-Career Investigator

- ***The ECI must clearly articulate their commitment to a career as an ovarian cancer clinical trialist and to participating in and contributing to the growth of the OCCTA.***
- *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, resources, and opportunities for establishing collaborations; or other obstacles.

- The Designated Mentor must be a clinical trialist with a strong record of mentoring and training ECIs. The Designated Mentor will serve as a resource to the ECI in designing and executing ovarian cancer clinical trial research to fit the research landscape. With the goal to establish and enrich the mentorship capabilities of the OCCTA, current Ovarian Cancer Academy (OCA) Designated Mentors cannot be named as a Designated Mentor in an FY25 application unless the period of performance of the current Ovarian Cancer Academy – Early-Career Investigator Award ends no later than July 2026. In the same manner, the Dean and Assistant Dean of the OCA or OCCTA cannot be listed as Designated Mentors.
- Research funded under this FY25 program announcement will ***support translational research and small-scale, early-phase clinical trials in ovarian cancer***. Examples of clinical trial focuses that are encouraged include but are not limited to diagnostic or prevention-focused studies, dietary or lifestyle interventions, therapeutic or surgical interventions, studies on quality of life, and repurposed drug trials.
- **Preliminary Data Are Required:** Inclusion of preliminary data relevant to the proposed clinical trial is required. ***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.***
- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of diverse populations in the clinical trial appropriate to the objectives of the study. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- **Intervention Availability:** The application should describe the plan and demonstrate the availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed study.
- **Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, knowledge of U.S. Food and Drug Administration (FDA) processes (if applicable), and data management. The application should identify coordinator(s) who will guide the clinical protocol through the local IRB of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual. The application should show strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities described in Code of Federal Regulations, Title 21, Part 312 (21 CFR 312), Subpart D, are fulfilled.
- **Consumer Advocates:** Applications are encouraged to include consumer advocate involvement. The consumer advocate is encouraged to be involved in the development of the research question, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project. As a lay representative, the consumer advocate must be an individual who has been diagnosed with ovarian cancer and should be active in an ovarian cancer advocacy organization. Their role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. Their role should be focused on providing objective input on

the research and its potential impact for individuals with, or at risk for, ovarian cancer. The consumer advocate should have a high level of knowledge of current ovarian cancer issues and the appropriate background and/or training in ovarian cancer research to contribute to the project.

- **Statistical Analysis and Data Management Plans:** The application should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study, and a data management plan that includes use of an appropriate database to safeguard and maintain the integrity of the data. If required by a Regulatory Agency, the trial must use a 21 CFR 11-compliant database and appropriate data standards.

3.2.2. Other Important Considerations for the Ovarian Cancer Clinical Trial Award – Early-Career Investigator

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 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.

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.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html. While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

Funding from this award mechanism must support a clinical trial. Applicants seeking funding for research that does not meet this definition should consider one of the other FY25 OCRP program announcements being offered.

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.***

Cost Cap: The application's total costs budgeted for the entire period of performance 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.

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.

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

Must be requested for:

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

May be requested for (not all-inclusive):

- Funding for the Designated Mentor(s)'s salary support (it is recommended that the requested salary amount to 5% of the Designated Mentor(s)'s annual salary to match efforts related to mentorship and participation in OCCTA activities).
- If applicable, funding for Other Mentor must be justified.
- Travel costs between collaborating organizations.
- Travel in support of multi-institutional collaborations.
- Costs associated with participating in the virtual OCCTA (e.g., hardware and/or software for the audio- or video-teleconferencing or web-based communications).
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required OCCTA meeting described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the OCRP Ovarian Cancer Clinical Trial Award – Early-Career Investigator.

Must not be requested for:

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

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 (eBRAP) 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:

  - **Research Idea**
    - Concisely state the project's objective and specific aims. Briefly describe the proposed project and the population(s) that will be enrolled in the study. Briefly describe the preliminary data and rationale including literature references supporting the proposed pilot clinical trial. Identify the population, access to the population, recruitment goals, including a brief description of the statistical plan.
  - **Clinical Impact**
    - Describe the potential impact of the proposed research and the impact on ovarian cancer or patient care/survivorship.
    - Explain why the proposed research is critical to the field.
  - **Career Development and Sustainment**
    - Describe the Early Career Investigator's career goals including a commitment to pursuing and sustaining a career as an ovarian cancer clinical trialist.
    - Briefly describe how the Designated Mentor and Other Mentor, if applicable, will assist the Early Career Investigator in becoming an independent ovarian cancer researcher and how their career will be sustained over time.
    - Describe the individualized career and professional development plan for the Early Career Investigator.

- **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.

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

  Describe the proposed project in detail using the outline below.

  – **Research Project and Feasibility:** 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. **The research project must be focused on ovarian cancer**.

  – Describe the type of clinical trial research to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to

show a clear course of action. The proposed research may start with translational research; however, a small-scale clinical trial must be developed in an official capacity during the period of performance. This clinical trial research can be a part of designated mentor's current/future clinical trial but needs to be focused on ovarian cancer and should be developed towards the ECI's own independent project. ***If a small-scale clinical trial requiring FDA approval is proposed, the application must include documentation of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application submission or approval (i.e., the file number of the application or the IND/IDE approval number).***

- 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.
- 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 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/or ethnic group and an accompanying rationale for the selection of subjects. It is not expected that every study will include all racial and/or ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race are exempt from this requirement.
- Identify the intervention to be tested and describe the projected outcomes. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care.
- Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the availability of, and access to, the appropriate patient population(s), as well as the ability to accrue sufficient subjects for the clinical trial. Provide readiness and/or anticipated first-patient-in date and a brief timeline for accrual and endpoints readout.
- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- **ECI's Career Goals:** Discuss the ECI's record of accomplishments, demonstrating the potential for becoming an independent investigator and ovarian cancer clinical trialist. Describe the ECI's career goals and plans in ovarian cancer clinical trials and how the proposed research and career development experience will promote an independent, sustainable career.
- **Integration of Career Development and Research:** 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 clinical trials.

- **Commitment to the OCCTA:** Describe why participation in the OCCTA is important in developing the ECI's career. Describe the ECI's motivation and commitment to participating in the OCCTA, to include networking and collaborating with other ECI/Designated Mentor pairs (and, if applicable, an Other Mentor) and the OCCTA 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 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.
  - **Letters of Collaboration:** 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.
- **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, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial 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. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- **Enrollment Plan:** Provide an anticipated enrollment table(s) for the inclusion of women and diverse populations using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. If the clinical trial study is a part of the Mentor's study, then the mentor's enrollment plan should be included during the course of trial. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of race and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. ***Studies utilizing previously collected human biospecimens/datasets or resources that cannot be linked to a specific individual, ethnicity, or race are exempt from this requirement and may submit "N/A" (to indicate not applicable) for this statement. If an application is adding an aim to an existing clinical trial to conduct biosample collection and biomarker analysis, use of the patients enrolled in that trial is expected and the study potentially may not include diverse populations. These applications are exempt from this requirement and may submit N/A for this statement.***
- **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 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.

  - **Background:** Present the ideas and rationale behind the proposed clinical trial.
  - **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:** Briefly describe how the proposed project will have an impact on research, patient care, and survivorship in ovarian cancer. Describe how the proposed research will make an important contribution toward the goal of eliminating 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.
  - **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.

- **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 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 OCCTA.
    - Describe the ultimate applicability of the research.
        - 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 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 (five-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format".

  For the Ovarian Cancer Clinical Trial Award – Early-Career Investigator, 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 Statement of Work (SOW).

- **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 peer-reviewed 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".**
    - Identify the sample population(s) that will participate in the proposed intervention, inclusive of diverse populations if applicable; describe how they represent the target population that would benefit from the intervention and describe the potential impact and anticipated outcomes of the proposed clinical trial on the lives and health of the target population. 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.
    - Describe any relevant controversies or treatment issues that will be addressed by the proposed clinical trial.
    - Describe any potential issues that might limit the impact of the proposed clinical trial.

  - Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
  - 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.
  - Explain how the proposed research will have an impact on the health and well-being of Service Members, Veterans, and their Family Members.

- **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 clinical research.
  - Describe the Designated Mentor's background and experience in clinical trial research, success in acquiring funding in clinical trial 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 OCCTA irrespective of their accomplishments as a researcher and mentor to other ECIs. Describe the Designated Mentor's motivation and commitment to participating in the OCCTA with the other ECI/Designated Mentor pairs and the OCCTA Leadership. Describe the Designated Mentor's commitment and time to serve as a secondary mentor to another ECI in the OCCTA.
- **Attachment 9: Other Mentor's Letter for the Ovarian Cancer Clinical Trial Academy – Early-Career Investigator 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 clinical 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 OCCTA with the other ECI/Designated Mentor pairs and the OCCTA Leadership.
- **Attachment 10: Statement of Eligibility (one-page limit): Upload as "Eligible.pdf".**

  Upload the Ovarian Cancer Clinical Trial Academy – Early-Career Investigator 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: 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 12: 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".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment 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 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.

(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".

4.4. 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.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525OCRPOCCTAECI from Grants.gov or eBRAP, depending on which submission portal will be used.

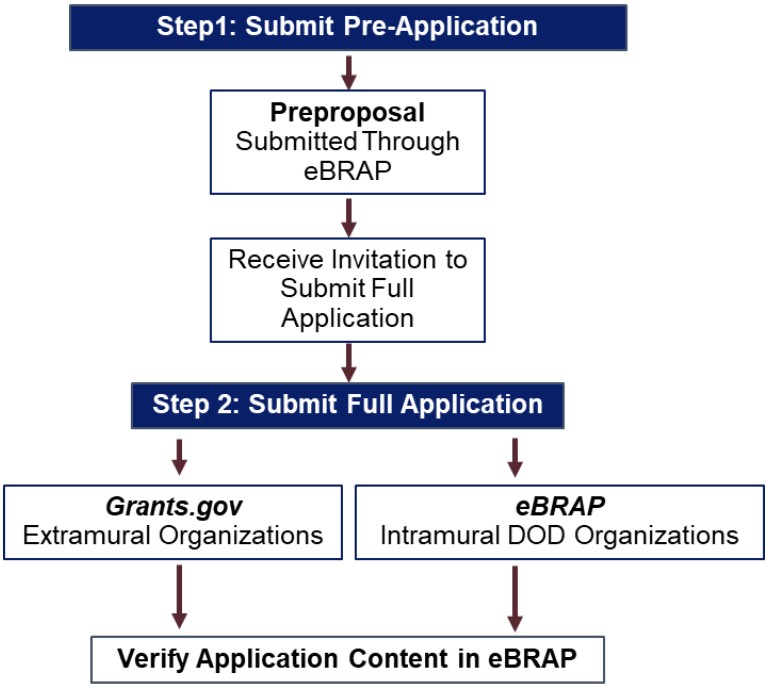
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, 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.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP.

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. 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.

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.

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 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 Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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 Section 9.2, Administrative Actions.

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:

- **Research Idea**
  - How well the rationale, project objectives, preliminary data, and specific aims support the research idea. To what extent the recruitment goals can be accomplished within the defined subject population**.** Whether the statistical plan is described.
- **Clinical Impact**
  - How well the potential impact of the proposed research and the impact on ovarian cancer or patient care/survivorship is described.
  - Whether the proposed research is critical to the field.
- **Career Development and Sustainment**
  - To what extent the Early-Career Investigator's stated career goals demonstrate a strong personal commitment to pursuing and sustaining a career as an ovarian cancer clinical trialist.

- The extent to which the Designated Mentor and Other Mentor will be supportive of the ECI's transition to independence and career sustainment over time.
- How well the individualized career and professional development plan will contribute to the overall development of the ECI.

6.2.2. Peer Review Criteria

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 clinical trialist.
  - The extent to which the ECI is motivated and committed to participating in the OCCTA with the other ECI/Designated Mentor pairs and the OCCTA 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 clinical trial 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 clinical trialist in ovarian cancer research.
- **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 OCCTA 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 clinical trial 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 clinical 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 OCCTA, and why they will be a "great" fit in the OCCTA irrespective of their accomplishments as a researcher and mentor to other ECIs.

- **Clinical Impact**
  - How impactful the anticipated outcomes of the proposed research study would be to the target population.
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - How the anticipated outcomes of the proposed study will provide/improve short-term benefits for individuals suffering from ovarian cancer.
  - How significantly the long-term benefits for implementation of the intervention may impact ovarian cancer patient care and/or quality of life.
- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed study is supported by the preliminary studies, preclinical data, review and analysis of the literature, and/or relevant ongoing, planned, or complete clinical trials.
  - How well the study questions, specific aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective and purpose.
  - If the proposed clinical trial is part of designated mentor's current/future clinical trial, how well the study is designed to become an independent study of the ECI's own independent research goals.
  - How the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
  - How the proposed study is designed with appropriate study variables, controls, and endpoints.
  - How well the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects are demonstrated.
  - How well the inclusion/exclusion criteria and group assignment process meet the needs of the proposed study.
  - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE application status (or other FDA approvals), if appropriate.
- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.

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**
  - To what extent the quality and level of organizational support are appropriate for the proposed research project.

- The extent to which the proposed research project and career development of the ECI are supported by the availability of facilities, equipment, staff, and other resources.
- If applicable, the degree to which the intellectual and material property plan is appropriate.

- **Budget**
  - 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.

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 ***and*** composition
  - Relative impact on ovarian cancer

6.3. Application Review and Selection Process

6.3.1. Pre-Application

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 Section 1, Basic Information about the Funding Opportunity. 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.

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

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.

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 6 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.

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 DoD R&D Terms and Conditions and the USAMRAA Research 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 Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), 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 (RPPR).

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).

8.3. Additional Requirements

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

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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.

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.
- 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 pre-application 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 CDMRP Website.
- 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) 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.
- The invited application proposes a different research project than that described in the pre-application.
- 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 proposed research does not contain clinical trial research.
- The Designated Mentor/Other Mentor (if applicable) does not meet the eligibility criteria.

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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
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"	☐
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 for the Ovarian Cancer Clinical Trial Academy – Early-Career Investigator Award application ***(if applicable)*** **– Attachment 9, upload as "OtherMentor.pdf"**	☐
Statement of Eligibility – Attachment 10, upload as "Eligible.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 11, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 12, upload as "IGBudget.pdf"**	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for PI and Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current and pending (other) support 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)***	☐

Appendix 2. Acronym List

ACOS/R&D	Associate Chief of Staff for Research and Development
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
ECI	Early-Career Investigator
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OCCTA	Ovarian Cancer Clinical Trial 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
RPPR	Research Performance Progress Report
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SOW	Statement of Work
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