

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Omics Consortium Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-OCR-OMCA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 24, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, July 08, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, July 13, 2021
- **Peer Review:** August/September 2021
- **Programmatic Review:** October/November 2021

This program announcement must be read in conjunction with the General Application Instructions, version 603. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2021 (FY21) Ovarian Cancer Research Program (OCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The OCRP was initiated in FY97 to provide support for research of exceptional scientific merit. Appropriations for the OCRP from FY97 through FY20 totaled \$371.45 million (M). The FY21 appropriation is \$35.0M.

II.A.1. Award History

The Omics Consortium Development Award mechanism was first offered in FY18. In FY18, three Omics Consortium Development Awards were funded, information about these awards can be found on the [CDMRP website](#). The Omics Consortium Development Award is being offered again in FY21.

The Omics Consortium Award mechanism is being offered for the first time in FY21.

II.B. Award Information

The FY21 OCRP Omics Consortium Award supports a multi-institutional research effort conducted by leading ovarian cancer researchers and consumers that specifically focuses on the compilation of new and/or use of existing large datasets to study the origin of ovarian cancer disease, with an emphasis on early detection and screening. This effort may be executed through a two-stage approach using two separate award mechanisms: the first is the Omics Consortium Development Award, which will enable the consortium to lay the groundwork for the research project, including a proof-of-concept preliminary research project; the second is an Omics Consortium Award, which will support the execution of the full research project. Research projects proposed under the Omics Consortium Development Award option or Omics Consortium Award option must use large datasets (genomics, proteomics, metabolomics, other “omics”) to focus on origin of disease. The long-term goal of the Omics Consortium is to facilitate improvements in early detection and screening of ovarian cancer, although immediate benefits of the consortium will be in initial diagnosis and therapy. With this in mind, applicants are encouraged to include rare subsets and putative pre-malignant lesions, as well as linkage to relevant interventional clinical trials, in the data gathered by the Omics Consortium Development Award.

The Omics Consortium Development Award:

The FY21 Omics Consortium Development Award provides support to:

- Develop the infrastructure of the consortium (e.g., building appropriate collaborations, outlining an administrative and management plan, developing a research and communication plan, and devising an intellectual property plan) and a multi-institutional research team inclusive of scientists, clinicians, and ovarian cancer consumers;
- Acquire research resources;
- Develop a plan to disseminate information regarding the procurement and distribution of data and/or biospecimens to the non-consortium ovarian cancer research community;
- Develop a detailed statistical plan with refined power analysis;
- Conduct a preliminary research project to demonstrate proof of concept;
- Prepare documents for obtaining approvals from local Institutional Review Boards (IRBs); and
- Develop informed consent forms, as applicable.

The Principal Investigator (PI), as the Consortium Director, is expected to have experience in successfully leading the design, administration, and management of multi-institutional research projects. The PI should create an environment that fosters and supports innovation and creativity, with consistent, intensive interaction within the research team in a way that engages all members of the consortium in all aspects of the research project. Research sites in this consortium should include scientists and/or clinicians who have made significant contributions to the field of ovarian cancer or who have specific expertise related to the research project. This award is meant to facilitate new collaborations. If support for a pre-existing consortium is proposed, then evidence of new collaborations must be apparent within the application. ***The research team must include (1) at least one Early-Career Investigator who is within 5 years of their last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent; (2) at least one ovarian cancer consumer; and (3) at least one Epidemiologist/Public Health Expert, all of whom should be integrally involved throughout the planning and implementation of the research project.*** As lay representatives, the consumers must be individuals who have been diagnosed with ovarian cancer and belong to an ovarian cancer advocacy organization. They must have a high level of familiarity and training involving current issues in ovarian cancer research, or a plan for such training should be included in the proposal. Consumers should be involved in the project design, recruitment, and evaluation, as well as other significant aspects of the proposed project. Interactions with other consortium members should be well integrated, ongoing, and not limited to attending seminars and semi-annual meetings.

The Omics Consortium Award:

Key Elements of the Omics Consortium award:

- **Consortium organization:** Describe the Consortium organization consisting of the multi-institutional research team of scientists, clinicians, and ovarian cancer consumers with a description of each of their roles and expertise. Include a description of data management and data sharing plans, as well as other plans as applicable.
- **Proposed research:** Provide the hypothesis or objective, and support using published or unpublished data. Include the proof of concept (**data, analysis, and discussion**) from the FY18 Omics Consortium Development Award or from other existing data and analysis if this is a new application. A statistical plan that includes a refined power analysis reflecting sample size projection must be submitted.
- **Research resources:** Provide a description of how the use of research resources (e.g., clinical specimens, databases, data sets, reagents) will be maximized. Include a description of how unnecessary duplication among consortium members will be minimized.

The FY21 Omics Consortium Award supports research focused only on the use of large datasets to study the origin of disease with an emphasis on early detection and screening. The scope of this research effort may include a broad spectrum of research spanning preclinical to clinical studies. Datasets may be newly generated or culled from existing resources. The research effort will provide immediate benefits for ovarian cancer patients in initial diagnosis and therapy and the end result will lead to improvements in early detection and screening detection of ovarian cancer. The consortium should comprise a multi-institutional research team made up of scientists and/or clinicians who have made significant contributions in the field of ovarian cancer. ***The research team must include (1) at least one Early-Career Investigator who is within 5 years of their last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent; (2) at least one ovarian cancer consumer; and (3) at least one Epidemiologist/Public Health Expert, all of whom should be integrally involved throughout the planning and implementation of the research project.*** The collaborations established through the consortium should be synergistic. The Consortium should maximize the use of resources and minimize unnecessary duplication among consortium members by sharing resources among all consortium members. The consortium should develop and execute a plan to establish financial independence from Department of Defense (DOD) funding by the end of the Omics Consortium Award period of performance. The OCRP Programmatic Panel and CDMRP staff members will serve as an external advisory board for the consortium.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, SC, et al. A call for transparent reporting to optimize the predictive value of preclinical research, [Nature 2012, 490:187-191](#).

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 FY21 OCRP priorities.

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

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY21 Omics Consortium Development Award will not exceed **\$400,000**. The anticipated direct costs budgeted for the entire period of performance for an FY21 Omics Consortium Award will not exceed **\$2.5M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately \$6.04M to fund approximately three Omics Consortium and 1 Omics Consortium Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections, Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical research is defined as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. Note: Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

PIs must be independent investigators at the Associate Professor level (or equivalent) or higher.

For the Omics Consortium Development Award, an Early-Career Investigator is defined as an investigator within 5 years of their last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent.

For the Omics Consortium Award, for new applications, the Early-Career Investigator is defined as an investigator within 5 years of their last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent. If the Early-Career Investigators on the three existing FY18 Omics Development Awards do not fit that definition any more they may continue; however if the Early-Career Investigator needs to be replaced in the Consortium Award, then the Early-Career Investigator is defined as an investigator within 5 years of their last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent.

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

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or 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).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

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

Submission is a two-step process requiring both *pre-application* (eBRAP.org) and *full application* (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application

submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

The application title, eBRAP log number, 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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://eBRAP.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

Select the appropriate mechanism option.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY21 OCRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

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

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

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

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

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the **same version** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-OCRP- OMCA from Grants.gov (https://www.grants.gov/) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-OCRP-OMCA from eBRAP (https://ebrap.org/).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General	Tab 1 – Summary: Provide a summary of the application information.

Extramural Submissions	Intramural DOD Submissions
Application Instructions, Section III.A.1, for detailed information.	Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form 	<p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>

Extramural Submissions	Intramural DOD Submissions
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (page limit varies by award option; see below for page limits): 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 that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed consortium that will focus on the origin of ovarian cancer disease with an emphasis on early detection and screening in detail using the outline below.

Omics Consortium Development Award (12-page limit):

- Describe the PI’s (Consortium Director) previous experience and accomplishments as they relate to the design, administration, and management of multi-institutional research projects.
- Provide a description of the projected consortium organization. If support for a preexisting consortium is proposed, then evidence of new collaborations must be apparent within the application. Include information regarding key participants at the Research Sites, including the Early-Career Investigator, the ovarian cancer consumer(s), and the proposed Epidemiologist/Public Health Expert and describe the significant contributions they have made to the field of ovarian cancer or their specific expertise related to identifying and understanding ovarian cancer origin of disease toward the success of the consortium. Named Research Sites (including the Early-Career Investigator), ovarian cancer consumer(s), and Epidemiologist(s)/Public Health Expert(s) must submit a letter of collaboration illustrating their commitment to developing a consortium to identify and understand the origin of ovarian cancer disease.
- Describe the integral roles that one or more consumer(s) will play in the planning, design, implementation, and evaluation of the proposed research project.
- Describe how the Epidemiologist(s)/Public Health Expert(s) is/are integrally involved in the research and management processes, with appropriate qualifications and background.
- Describe how the infrastructure includes building appropriate collaborations, and outline an administrative management plan, a research and communication plan, and an intellectual property plan.

- Describe the proposed research that focuses on the compilation of new and/or use of existing large datasets to aid in identifying and understanding the origin of ovarian cancer disease with emphasis on early detection and screening. Present the ideas and reasoning behind the proposed research, to include relevant literature citations. State the hypothesis to be tested or the objective(s) to be attained.
- Describe the preliminary statistical plan for the proposed preliminary research project to demonstrate proof of concept. Include a preliminary power analysis that reflects the sample size projections proposed to address the hypothesis and/or the objectives of the project.
- Describe the availability of the necessary research resources, as determined by the preliminary power analysis, and a brief summary of the plan for acquiring these research resources. Resources must include large datasets; these may include databases providing information on genomics, proteomics, metabolomics, clinical outcomes/treatments, and biospecimens. Include how unnecessary duplication of resources among consortium members will be minimized.
- Describe the strategy for the inclusion of minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of racial, and/or ethnic group, and an accompanying rationale for the selection of subjects.
- Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.
- Describe a plan to disseminate information regarding the procurement and distribution of data and/or biospecimens to the non-Consortium ovarian cancer research community.

Omics Consortium Award (20-page limit):

Describe the proposed research project that will focus on identifying and understanding the origin of ovarian cancer disease using the general outline below:

- Describe the proposed research that focuses on the compilation of new and/or use of existing large datasets to aid in identifying and understanding the origin of ovarian cancer disease. Present the ideas and scientific reasoning behind the proposed research, to include relevant literature citations.
- Provide the proof of concept. Include an analysis and discussion of these data.
- State the hypothesis to be tested or the objective(s) to be reached in this FY21 Omics Consortium Award.
- Provide the statistical plan for the proposed research project, including a power analysis that reflects the sample size projections proposed to address the hypothesis and/or the objectives of the project.

- Describe the milestones and research outcomes anticipated at the end of the project.
- Describe the Consortium organization to include all key participants. Include an organizational chart as well as the role and background, qualifications and expertise of each collaborator in the research project. Describe the integral role(s) that one or more consumer(s) has played and will play in the planning, design, implementation, and evaluation of the proposed research project. Describe how the consortium members will coordinate and function as an integrated team and minimize unnecessary duplication.
- Describe the data collection, management, analysis, sharing plans, and other plans (e.g., communication) for the Consortium. Outline the plan(s) to monitor quality and consistency of methods, data collection and analysis. Briefly describe plans for the timely publication of major findings and dissemination of results to the ovarian cancer community.
- Describe the availability of the necessary research resources, as determined by the preliminary power analysis, and a brief summary of the plan for acquiring these research resources. Resources must include large datasets; these may include databases providing information on genomics, proteomics, metabolomics, clinical outcomes/treatments, and biospecimens. Include how unnecessary duplication of resources among consortium members will be minimized.
- Describe the strategy for the inclusion of minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of racial, and/or ethnic group, and an accompanying rationale for the selection of subjects.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration:** Provide a signed letter from each of the proposed research site PIs including the Early-Career Investigator, ovarian consumer(s), and Epidemiologist(s)/Public Health Expert(s) that describes their commitment and how they will support the consortium PI and the consortium.
- **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (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.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from 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. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution 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. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. Technical abstracts should be written using the outline below: Technical abstracts should be written using the outline below:

- Background: Present the research focus behind the proposed consortium.
- Objective/Hypothesis: State the hypothesis to be tested or the objective(s) to be attained.
- Provide rationale that supports the hypothesis to be tested or the objective(s) to be attained.
- Study Design: Briefly describe the consortium design, organization, and interactions.
- Impact: Summarize briefly how the proposed research project will have an impact on understanding the origins of disease.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the ovarian cancer consumer community.

Do not duplicate the technical abstract. Lay abstracts should be written using the outline below:

- Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
- Describe the ultimate applicability of the consortium’s research, including short-term and long-term impact.

- What are the potential applications, benefits, and risks?
- What is the projected time it may take to achieve a patient-related outcome?
- How will the development of this consortium enhance and advance the field of ovarian cancer research?
- How will the preliminary research project impact the short-term goals of benefits in diagnosis and therapy and the long-term goals of early detection and screening?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested Statement of Work (SOW) format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Omics Consortium Development Award or Omics Consortium Award mechanism, refer to the “*Suggested SOW Strategy Generic Research*” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”**
 - **For the Omics Consortium Development Award:** Describe the ultimate vision for how the preliminary research project, if successful, will have a significant impact on identifying and understanding the origins of disease. Discuss the immediate impacts on initial diagnosis and therapy as well as the potential long-term improvements in early detection and screening of ovarian cancer. Describe the research plan for the proposed proof of concept study that will generate sufficient data to adequately support this research project when submitted to the FY23 Consortium Award funding opportunity.
 - **For the Omics Consortium Award:** Describe how the proposed research project will provide immediate impact for ovarian cancer patients in initial diagnosis and therapy and the end result will lead to improvements in screening and early detection of ovarian cancer.
- **Attachment 7: Inclusion of Women and Minorities Inclusion Enrollment Report format: Upload as “IWAM.pdf”.** If applicable, provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The suggested Inclusion Enrollment Report format, Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>.

- **Attachment 8: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 9: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>, including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

- For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf”.
 - Include biographical sketches for collaborators at each Research Site.
 - Include biographical sketch(es) for consumer(s).
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - Include current/pending support for the collaborators at each Research Site.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf”. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as Attachment 9. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified.

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, *with the exception of the Project Narrative and Budget Form*, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

For the **Omics Consortium Development Award**, the maximum period of performance is **2** years.

The anticipated direct costs budgeted for the entire period of performance for the **Omics Consortium Development Award** will not exceed **\$400,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$400,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

For the **Omics Consortium Award**, the maximum period of performance is **4** years.

The anticipated direct costs budgeted for the entire period of performance for the Omics Consortium Award will not exceed **\$2.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$2.5M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

- For this award mechanism, direct costs must be requested for the **Omics Consortium Award**. Travel costs for the PI and senior/key personnel to present project information or disseminate project results at a DOD OCRP milestone meeting during the period of performance in year 3 should be requested. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all inclusive):

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the OCRP Omics Consortium Development Award or OCRP Omics Consortium Award.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

For the **Omics Consortium Development Award**:

- **Consortium Structure**
 - Whether the consortium includes Research Sites with named scientists and/or clinicians who have made significant contributions to the field of ovarian cancer or who have specific expertise related to identifying and understanding ovarian cancer origin of disease.
 - Whether the consortium includes at least one Early-Career Investigator, one ovarian cancer consumer, and at least one Epidemiologist/Public Health Expert.

- How well the infrastructure includes building appropriate collaborations, outlining an administrative management plan, developing a research and communication plan, and devising an intellectual property plan.
- How well the Research Sites will maximize the use of resources and minimize unnecessary duplication of resources.
- Whether the consortium includes a plan for dissemination of information to the non-Consortium ovarian cancer research community.
- **Personnel**
 - How well the PI's (Consortium Director) experience and accomplishments demonstrate appropriate expertise in the design, administration, and management of multi-institutional research projects.
 - How the consortium team's (including the Early-Career Investigator) background and expertise are appropriate for accomplishing the goal of identifying and understanding the origin of ovarian cancer disease.
 - How well the consortium participants are committed to developing a consortium to identify and understand the origin of ovarian cancer disease.
 - How the consumer(s) is/are integrally involved in the planning, design, implementation, and evaluation of the proposed project, with appropriate qualifications and background.
 - How the Epidemiologist(s)/Public Health Expert(s) is/are integrally involved in the research and management processes, with appropriate qualifications and background.
- **Research Project**
 - How well the application describes the proposed research project and whether it focuses on the compilation of new and/or use of existing large datasets to aid in identifying and understanding the origin of ovarian cancer disease with emphasis on early detection and screening.
 - Whether the application includes a statistical plan and a preliminary power analysis that reflects the sample size projection proposed to address the hypothesis and/or the objective(s) of the proposed project.
 - How the plan for acquiring the necessary research resources is sufficient for the proposed research project.
 - Whether the application outlines how approvals will be obtained from local IRBs and how the informed consent process will be initiated, if applicable.
 - Whether the strategy for the inclusion of minorities and distribution of proposed enrollment are appropriate for the proposed research.

- **Proof of Concept**

- How the research plan for the proposed proof of concept study will provide sufficient data to adequately support the proposed research project when submitted to the FY23 Consortium Award funding opportunity.

- **Impact**

- How the consortium structure and overall approach will lead to the effective identification and understanding of the origin of ovarian cancer disease.
- Whether the immediate benefits in initial diagnosis and therapy are clear. Whether the long-term goal of improvements in early detection and screening are well described.

For the **Omics Consortium Award**:

- **Consortium Organization**

- How well the consortium team's background, qualifications, and expertise are appropriate for their proposed roles and are complementary. To what extent the consortium members plan to coordinate and will function as an integrated team.
- To what degree the levels of effort by the PI and key personnel will ensure success of the proposed work.
- To what extent the consumer(s) is integrally involved in the planning, design, implementation, and evaluation of the proposed research project.
- How well the consortium members coordinate and function as an integrated team to minimize unnecessary duplication.

- **Research Project**

- How well the application describes the proposed research project.
- To what extent the research project focuses on the compilation of new and/or use of existing large datasets to aid in identifying and understanding the origin of ovarian cancer disease.
- How well the data, analyses and discussion from the proof of concept support the proposed research.
- To what extent the statistical plan and power analysis reflect sample size projection, and will address the hypothesis and/or the objective(s) of the proposed project.
- To what extent the availability of, and accessibility to, and/or acquisition of the necessary research resources will impact the goal of the proposed research project.
- To what extent the anticipated milestones and research outcomes are achievable.

- Whether the strategy for the inclusion of minorities and distribution of proposed enrollment are appropriate for the proposed research.
- **Impact**
 - To what extent the proposed research project will provide immediate impact for ovarian cancer patients in initial diagnosis and therapy.
 - To what extent these results will lead to improvements in screening and early detection of ovarian cancer.
- **Data Management and Sharing**
 - How well the overall approach to data collection, management, analysis, and sharing within the Consortium is described.
 - To what extent the Consortium plans to monitor quality and consistency of methods, data collection and analysis.
 - How well the plans are outlined for the timely publication of major findings and dissemination of results to the ovarian cancer community.

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

- **Budget**
 - Whether the **direct** costs exceed the **allowable direct** costs as published in the program announcement.
 - Whether the budget is appropriate for the proposed research.
- **Environment**
 - If applicable, to what degree the intellectual and material property plan is appropriate
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY21 OCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***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 II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the OCRP will be provided to the PI and posted on the CDMRP website.

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

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit 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. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. 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.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, 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 2, Section B, for general information on organization or PI changes.

II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

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

Inclusion Enrollment Reporting Requirement: Enrollment on the basis of race and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from this program announcement will incorporate 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 \$10.0M are required to provide information to FAPIIS 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. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

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

Questions related to this program announcement should refer to the Program name, the program announcement name, and the program announcement version code 603a. The program announcement numeric version code will match the General Application Instructions version code 603.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY21 OCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY21 OCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/ocrp/panels/panels21>.*
- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- 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 may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- 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.
- An application for which an Early-Career Investigator or an ovarian cancer consumer, or an Epidemiologist/Public Health Expert is not included on the research team
- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact and Proof of Concept Statement: Upload as Attachment 6 with file name "ImpactProof.pdf."	
	Inclusion of Women and Minorities Inclusion Enrollment Report format: Upload as Attachment 7 with file name "IWAM.pdf".	
	Representations (extramural submissions only): Upload as Attachment 8 with file name "RequiredReps.pdf" if applicable	
	Suggested DOD Military Facility Budget Format: Upload as Attachment 9 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget (extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget (intramural submissions only)	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FY	Fiscal Year
HRPO	Human Research Protection Office
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OCRP	Ovarian Cancer Research Program
ORCID	Open Researcher and Contributor ID, Inc.
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs