

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Melanoma Research Program**

**Translational Research Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-20-MRP-TRA**

**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 22, 2020
- **Invitation to Submit an Application:** July 28, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, September 24, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, September 30, 2020
- **Peer Review:** December 2020
- **Programmatic Review:** February 2021

*This Program Announcement must be read in conjunction with the General Application Instructions, version 501. 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 2020 (FY20) Melanoma Research Program (MRP) 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 MRP was initiated in 2019 to provide support for research of exceptional scientific merit in the field of melanoma. Appropriations for the MRP in FY19 totaled \$10 million (M). The FY20 appropriation is \$20M.

*The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.*

*The goal of the MRP is to prevent melanoma initiation and progression. The mission of the MRP is to support earlier intervention to enhance mission readiness for U.S. military personnel and to diminish the disease burden on Service members, Veterans, and the American public.*

#### II.A.1. FY20 MRP Focus Areas

**FY20 MRP Challenge Statement:** The MRP challenges the research community to redefine the concept of prevention. Melanomagenesis is a multi-step process initiating from normal melanocytes to dysplasia, through the development of melanoma and metastasis. A new paradigm of prevention may include detection, monitoring, and stopping the initiation of dysplasia, halting the progress to malignancy, blocking micro-metastases, or preventing emergence from tumor dormancy. The MRP acknowledges that each step along the disease process from initiation to metastasis is an opportunity to detect, monitor, and impede progression and to effect a cure. The MRP challenges the research community to prevent melanoma earlier in the disease cycle, thus preventing metastasis. The melanoma clinical, research, and patient community traditionally view prevention as the use of sunscreen/blockers to protect the melanocyte from harmful ultraviolet (UV) radiation. The MRP recognizes the usefulness of this strategy while tasking the research community *to redefine prevention to include the entire melanomagenesis process*. For more information on the MRP Challenge Statement, review <https://cdmrp.army.mil/mrp/pdfs/Challenge%20statement.pdf>. The FY20 MRP Focus Areas promote the role of prevention throughout the disease process.

*The MRP encourages studies for rare melanomas across the entire spectrum from initiation to distant macro-metastasis.*

To be considered for funding, applications for the FY20 MRP Translational Research Award *must* address at least one of the FY20 MRP Focus Areas.

- **Prevention of melanoma initiation factors** (e.g., UV radiation)
- **Prevention of melanomagenesis and precursor lesions** (e.g., novel genetic and epigenetic drivers, oncogene induced senescence)
- **Understanding the tumor microenvironment**
  - Primary Tumor
  - Regional Nodes
  - Distal Nodes
- **Bioengineering (e.g., computational, imaging) approaches to address diagnostics, high risk markers, dormancy, and metastasis**
- **Therapeutic Prevention** (e.g., interruption of disease progression, recurrence)
- **Minimal Residual Disease** (e.g., chemoprevention, micro-metastasis)

*The MRP strongly encourages the use of Department of Defense (DoD)/Department of Veterans Affairs (VA) databases and participation by DoD/VA investigators.*

## **II.B. Award Information**

The FY20 MRP Translational Research Award (TRA) supports hypothesis-driven, translational, *high-impact* research. The TRA mechanism encourages applications with mature research projects that specifically focus on critical scientific or clinical melanoma issues, which, if successfully addressed, have the potential to make a major impact. *Important factors under consideration will be continuity of research, clinical applicability, and leveraging of clinical samples from clinical trials and/or biorepositories.* The TRA supports identifying scientific outcomes, through rigorous, robust research, that are translatable toward treatment and/or preventive strategies. Proposed research should be mature and well developed. Research proposed should aim to accelerate promising findings toward clinical applicability and leverage research results to maximize impact. The TRA is *not* intended to study research into clinical utility of PD-1 in combination with other therapeutics, or studies utilizing established cell lines.

*With the exception of those studies investigating rare melanomas, the FY20 MRP is not requesting research into established macrometastatic disease, models of metastatic disease using established cell lines, or treatment of macrometastatic disease. The MRP encourages studies for rare melanomas across the entire spectrum from initiation to distant macro-metastasis.*

*Studies involving non-melanoma skin cancers are not allowed under the FY20 MRP.*

**The critical components of this award mechanism are:**

- **Translation:** The TRA is intended to support research that demonstrates the potential to have a major impact on an area of paramount importance in melanoma. The proposed study should demonstrate how the research will be translated to improved patient outcomes in at least one of the FY20 MRP Focus Areas and addresses the FY20 MRP Challenge Statement. The research should make a significant shift toward clinical applicability in at least one of the FY20 MRP Focus Areas. The applicant must articulate the potential translational impact the proposed project will have on melanoma research and/or patient outcomes. Translational research will, if successful, accelerate the movement of promising ideas into clinical applications. The TRA is intended to support established projects that have moved beyond the realm of basic research and have the potential to result in a near-term impact in clinical research or the clinic. *Clinical trials are not allowed.*
- **Preliminary Data:** The TRA is intended to support translational investigations that leapfrog the melanoma research field forward by utilizing previous research findings. The TRA is not intended for basic research to generate preliminary data. All applications intent on generating preliminary data should apply to the FY20 MRP Idea Award (**W81XWH-20-MRP-IA**). TRA applications *must include preliminary data* to support feasibility of the study. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member(s) of the research team.
- **Correlative Research:** Studies funded by the TRA should leverage clinical samples from established biobanks, biorepositories, and/or ongoing or completed clinical trials. Clinical samples should inform laboratory research. The outcomes of the proposed research should reciprocate and inform the clinic. This synergistic integration between the laboratory and clinic should lead to greater knowledge, discovery, and development of earlier interventions to prevent melanoma initiation and progression. *Funding for clinical trials is not allowed under the FY20 MRP TRA. Meta-analysis and/or studies exclusively utilizing patient medical files do not respond to the intent of the TRA.*
- **Collaborator Option:** As a method to facilitate progress in addressing critical problems or questions through collaborative efforts, the FY20 MRP is offering a Collaborator Option for this award mechanism. The results of this collaborative project should significantly advance the research beyond what would be possible through individual efforts. The Collaborator Option is structured so that two investigators, each of whom will be designated as a PI, work synergistically on a single project. Each PI should bring complementary skills and perspectives to the research project. It is encouraged that one PI be a clinician and the other PI be laboratory based. Developing the research plan should involve an equitable flow of ideas and information between the partners. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Each PI must demonstrate that they possess the research experience and resources to function as a PI and must also exhibit an appropriate level of authority and responsibility to direct the project supported by the awards. *New and multi-institutional collaborative efforts are strongly encouraged.* PIs should include plans for communication between investigators at different organizations, if applicable. Additionally, participating organizations must be willing to resolve potential

intellectual and material property issues and to remove any barriers that might interfere with achieving high levels of cooperation to ensure successful completion of the proposed research project.

For the Collaborator Option, one PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. Initiating and Partnering PIs each have different submission requirements, as described in [Section II.D.2, Content and Form of the Application Submission](#); however, both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, SOW, and other required components. If recommended for funding, each PI's organization will receive their own separate award. ***A separate application submission is required for each PI, even if both PIs are at the same organization.*** Additional collaborators may be included in the application without being designated as PIs.

***The MRP encourages inclusion of military or VA investigators as an equal partner in the research, offering both intellectual investment and research effort.***

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 FY20 MRP priorities.

Applications submitted under the Collaborator Option are allowed to request a higher direct cost budget than applications submitted with a single PI (see [Section II.D.5, Funding Restrictions](#), for details). Costs should be divided as evenly as possible between both partners unless appropriately justified, but no more than 75% (or no less than 25%) of the proposed direct costs may be requested by a single partner. Submission of a [Collaborative Statement, Attachment 8](#), is required for applications submitted under the Collaborator Option.

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 FY20 MRP Translational Research award will not exceed **\$600,000**. The anticipated direct costs budgeted for the entire period of performance for an FY20 MRP TRA – Collaborator Option will not exceed **\$700,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

*The CDMRP expects to allot approximately \$1.92M to fund approximately two (2) Translational Research Award applications and \$2.24M to fund approximately two (2) Translational Research Award – Collaborator Option 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 FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.*

**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 (ORP), 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 Subject Resource 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 trials are not allowed.**

***A clinical trial is defined*** as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other

control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**Use of DoD or VA Resources:** If the proposed research involves access to active duty military patient populations and/or DoD 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.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** All organizations, including 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**

To be named as the PI on the application, the investigator must be at or above the level of Assistant Professor (or equivalent).

#### **Collaborator Option:**

The Initiating and Partnering PI must be at or above the level of Assistant Professor or equivalent. Inclusion of a military or VA investigator is encouraged.

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](http://eBRAP.org).
- Full application packages must be accessed and submitted at [Grants.gov](http://Grants.gov).

#### ***Intramural DoD Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).

- Full application packages must be accessed and submitted at [eBRAP.org](http://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](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

**For Collaborative Option Applications:** The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. *The Partnering PI must follow the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, the Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.* If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

#### **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](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

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

The applicant organization(s) and associated PI(s) 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](mailto:help@eBRAP.org) or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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.

- **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 PIs 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.

[FY20 MRP 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](mailto:help@eBRAP.org) or 301-682-5507.

The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **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**

**Note:** *Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

- **Preproposal Narrative (two-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:

- State the project’s hypothesis, objectives, rationale, and specific aims. Describe the methodology and experimental design that support the hypothesis/objectives and will appropriately test the specific aims.
- Demonstrate how the research is based on strong preliminary data. Describe the **potential near-term impact** of the proposed research.
- Describe how the project will leverage clinical samples from established biobanks, biorepositories, and/or ongoing or completed clinical trials. Explain how the clinical

samples will inform laboratory research. Describe the synergistic integration between the laboratory and clinic.

- Identify the FY20 MRP Focus Area(s) in [Section II.A.1](#) to be studied. Explain how the proposed research will lead to promising outcomes for one or more of the selected FY20 MRP Focus Area(s) and responds to the FY20 MRP Challenge Statement.
- **Collaborator Option:** Identify roles, responsibilities, and discipline of each team member and explain how they integrate to form a synergistic team.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
  - References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - Key Personnel Biographical Sketches (five-page limit per individual). *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the MRP, pre-applications will be screened based on the following criteria:

- How well the methodology and experimental design support the hypothesis/objectives and test the specific aims.
- Whether the preliminary data support the proposed research.
- Whether the project will leverage information from biobanks, biorepositories, ongoing or completed clinical trials. To what extent the clinical samples will inform laboratory research.
- Whether there is evidence of synergistic integration between the laboratory and clinic.

- Whether the proposed project addresses at least one of the FY20 MRP Focus Areas in [Section II.A.1](#). How the proposed research will lead to promising outcomes for one or more of the selected FY20 MRP Focus Area(s) and responds to the FY20 MRP Challenge Statement.
- **Collaborator Option:** How well the roles, responsibilities, and discipline of each partner, integrate to form a synergistic team.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

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

*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
<b>Application Package Location</b>	
<p>Download application package components for W81XWH-20-MRP-TRA from Grants.gov (<a href="https://www.grants.gov">https://www.grants.gov</a>) 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.</p>	<p>Download application package components for W81XWH-20-MRP-TRA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</p>
<b>Full Application Package Components</b>	
<p><b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> </ul>	<p><b>Tab 3 – Full Application Files:</b> 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"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> 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 <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> 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. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> 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. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><u><a href="#">Application Verification Period</a></u></b>	
<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 <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI (s) 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 <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> 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>



Extramural Submissions	Intramural DoD Submissions
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> 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 CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Initiating PI’s and Partnering PI’s) must be submitted by the full application submission deadline.*

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. *It is important to include the attachment name as a header on each page of the attachment files.*

- **Attachment 1: Project Narrative (10-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 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 project in detail using the outline below. *Inclusion of preliminary data is required.*

- **Background:** Describe the critical scientific or clinical issue that, if successfully addressed, will have a major impact on at least one of the FY20 MRP Focus Areas in [Section II.A.1](#) and responds to the FY20 MRP Challenge Statement. Include preliminary data and reconcile it with objectives of the research proposed. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the PI(s) or collaborators named on this application and/or data from the published literature relevant to the proposed research project *must* be included.
- **Hypothesis and Objective:** State the hypothesis to be tested and the objective to be reached regarding an important problem relevant to at least one of the FY20 MRP Focus Areas.
- **Specific Aims:** State the specific aims of the study.
- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources. Describe how the project will leverage clinical samples from established biobanks, biorepositories, and/or ongoing or completed clinical trials. Describe how the clinical samples will inform the laboratory investigations. Address potential problem areas and potential pitfalls, and present alternative methods and approaches. Describe the statistical plan and justify how it is appropriate for the experimental methodology being used. Describe the power analysis for the proposed study and that it adequately represents an assessment of the population or subpopulation proposed. Research projects may include preclinical studies in animal models or clinical research involving human anatomical substances. If animal studies are proposed, explain the choice of model and describe the endpoints/outcome measures to be used. If human anatomical samples will be used, include a plan for the acquisition of samples. *Funding for Clinical trials are not allowed.*
- **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 (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- 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.
  - 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 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.
  - **Background:** State the FY20 MRP Focus Area(s) in [Section II.A.1](#) to be addressed by the proposed research. Describe how the FY20 MRP Challenge Statement will be addressed. Present the ideas and reasoning behind the proposed work. Describe how the project will leverage clinical samples from established biobanks, biorepositories, and/or ongoing or completed clinical trials.
  - **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Briefly describe the study design and methodology.
  - **Impact:** Briefly describe how the proposed project will have an impact on at least one of the FY20 MRP Focus Areas. Explain how the clinical samples will inform laboratory research. Describe the synergistic integration between the laboratory and clinic.
  - **Collaborator Option:** Describe how the project depends on the unique skills and expertise of each partner. Describe how the proposed collaboration involves a

substantial contribution by each partner and the reciprocal flow of ideas and information.

- **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.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

- State the FY20 MRP Focus Area(s) to be addressed by the research project. Describe how the FY20 MRP Challenge Statement will be addressed.
  - 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.***
  - In lay persons’ terms: Describe the impact and ultimate applicability of the research. What types of patients will it help, and how will it help them? What are the potential clinical applications, benefits, and risks? What is the projected time it may take to achieve a patient-related outcome? What are the likely contributions of this study to advancing at least one of the FY20 MRP Focus Areas?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested 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>). For the TRA mechanism, use the SOW format example titled, “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- Identify cell line(s) and commercial or organizational source(s) to be used.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

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

○ **Attachment 6: Source and Quality Assessment of Samples (one-page): Upload as “SQASamples.pdf”.**

- Indicate the source of study samples. Indicate the name, position of the manager or lead investigator of the source of samples. This should be the same person providing the Letter of Resource Support (see [Attachment 7](#)).
- Investigators intending to use banked specimens should include a description of steps that will be taken to assess the quality of the materials and to identify and correct for effects and/or artifacts of sample processing and storage. Outline the development of standardized methods sample assessment.
- If the resource is an ongoing or completed clinical trial, include a description of the sample collection procedures, the assessment of the materials, and the evaluation for effects and/or artifacts of sample processing and storage.

○ **Attachment 7: Letter of Resource Support (two-page limit): Upload as “Resource.pdf”.**

- Provide a signed letter(s) from the manager(s) or lead investigator(s) for the biobank(s), biorepository(s), ongoing or completed clinical trial(s) detailing access to the samples and/or resource.
- If the resource is an ongoing clinical trial, provide a letter from the lead investigator detailing the recruitment of human subjects as well as validating the status of the clinical trial as ***open and actively recruiting*** (number of recruited patients, percent of total recruited patients should be included). If the clinical trial is closed, the letter should indicate the recruitment accomplished, the quality and standardization of the samples.

○ **Attachment 8: Collaborative Statement (one-page limit) (if applicable): Upload as “Collaborative.pdf”. *This attachment is only required for applications submitted under the Collaborator Option.***

Describe the expertise of the Initiating and Partnering PIs and how each will bring different strengths to the proposed project. Describe how the combined effort will be synergistic and produce an outcome greater than what could be achieved by independent

efforts. Outline the contribution and time commitment of each PI and how each will have equal intellectual input on the design, conduct, and analysis of the project. Describe how the PIs will manage the collaboration and workflow to optimize research efforts.

- **Attachment 9: Research Outcomes Plan: (one-page limit): Upload as “Outcomes.pdf”.** Describe the anticipated research outcomes including knowledge products, clinical products for development, etc. Describe the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project. Detail the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for). Demonstrate that a plan for management of intellectual property is in place.
  - **Attachment 10: Impact Statement (one-page limit): Upload as “Impact.pdf”.** *The Impact Statement should be written in plain language for lay persons.* Explain how the clinical samples will inform laboratory research and, in turn, will lead to promising findings with clinical applicability and new avenues for patient outcomes. Discuss the near-term clinical impact to patients. State how the research will leverage results to maximize impact. State explicitly how the proposed work addresses a critical problem in at least one of the FY20 MRP Focus Areas in [Section II.A.1](#). Describe how the study addresses the FY20 MRP Challenge Statement and how it will lead to changes in clinical care.
  - **Attachment 11: 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 12: 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 A§1681 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 (NIH) 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”.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.

**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.

*Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

**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 12](#). (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.

**Suggested DoD Military Budget Format:** A military facility collaborating in the performance of the project (but not participating as a Collaborating PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using “Suggested Collaborating DoD Military Facility Budget Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [\[https://ebrap.org/eBRAP/public/Program.html\]](https://ebrap.org/eBRAP/public/Program.html) (Attachment 12) to show all direct and indirect costs. 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.

<b>Application Components for the Partnering PI</b>
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The Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in [Section II.C.1.a, Organization](#)) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

**Attachments:**

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the General Application Instructions, Section III.A.2, for detailed information on

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

- **Attachment 11: Representations (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 12: Suggested Collaborating DoD Military Facility Budget Format: Upload as “MFBudget.pdf”.** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

**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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch\_LastName.pdf”.
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.

**Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.

*Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include*

*budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

**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 General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form:**

- **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.)
- **Intramural DoD Collaborator(s):** Complete a separate DoD military budget, using Suggested Collaborating DoD Military Facility Budget Format (available for download on the eBRAP “Funding Opportunities & Forms” web page [\[https://ebrap.org/eBRAP/public/Program.htm\]](https://ebrap.org/eBRAP/public/Program.htm)), and upload to Grants.gov attachment form as Attachment 14. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

### **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 December 2020, 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(s) 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**

The maximum period of performance is **3** years.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. 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 \$600,000 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.

**Collaborative Option:** The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and Partnering PI's applications will not exceed \$700,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed \$700,000 or use an indirect cost rate exceeding each organization's negotiated rate.

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

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

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

For this award mechanism, direct costs may include travel costs:

- Travel in support of multidisciplinary collaborations.
- Costs for two investigators to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the MRP TRA.

Must not be requested for:

- Clinical trials

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:

- **Research Strategy and Feasibility**
  - Whether the critical scientific or clinical issue that, if successfully addressed, will have a major impact on at least one of the FY20 MRP Focus Areas in [Section II.A.1](#) and respond to the FY20 MRP Challenge Statement.
  - Whether the preliminary data reconciles with the objectives of the research proposed.
  - To what extent the experimental design, methods, and analyses are sufficiently detailed, including whether the application describes availability of resources.
  - Whether the project will leverage clinical samples from established biobanks, biorepositories, and/or ongoing or completed clinical trials. To what degree the clinical samples will inform the laboratory investigations.
  - To what degree the statistical plan is appropriate for the experimental methodology being used. Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.
  - How well the application acknowledges potential problems and pitfalls, and addresses alternative approaches.
  - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable.
- **Source and Quality Assessment of Samples**
  - Whether the application identifies the source of the study samples.
  - Whether the supporting letter from the manager or lead investigator of the sample resource demonstrates a commitment of resources to the study.
  - If the source is a biobank or biorepository, whether the application provides details on the steps to be taken to assess the quality of the materials and to identify and correct for effects and/or artifacts of sample processing and storage.

- If the resource is an ongoing or completed clinical trial, whether the application provides details on the sample collection procedures, the assessment of the materials, and the evaluation for effects and/or artifacts of sample processing and storage.
- **Impact**
  - To what degree the clinical samples will inform laboratory research and, in turn, lead to promising findings with clinical applicability and new avenues for patient outcomes.
  - Whether the research will lead to near-term clinical impact for patient outcomes. How well the research will leverage results to maximize impact.
  - Whether the proposed work addresses a critical problem in at least one of the FY20 MRP Focus Areas in [Section II.A.1.](#)
  - Whether the study addresses the FY20 MRP Challenge Statement and how it will lead to changes in clinical care.
- **Research Outcomes Plan**
  - Whether the application described the anticipated research outcomes including knowledge products, clinical products for development, etc.
  - How well the application demonstrated methods and strategies to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project.
  - Whether the application detailed the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
  - Whether a plan for management of intellectual property is in place.
- **Collaborator Option (if applicable):**
  - To what extent the expertise of the Initiating and Partnering PI bring different strengths to the proposed project.
  - To what extent combined effort will be synergistic and produce an outcome greater than what could be achieved by independent efforts.
  - Whether the application outlines the contribution and time commitment of each PI and how each will have equal intellectual input on the design, conduct, and analysis of the project.
  - How the PIs will manage the collaboration and workflow to optimize research efforts.

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

- **Personnel**
  - Based on the budget justification, how appropriate the levels of effort are for successful conduct of the proposed work.
  - Based on the biographical sketches, how appropriate is the expertise of the research team.
- **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**
  - To what degree the scientific environment is appropriate for the proposed research.
  - To what degree the quality and extent of institutional support are 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 FY20 MRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relevance to the FY20 MRP Focus Areas and the FY20 MRP Challenge Statement
  - Relative impact
  - Translational potential

#### **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 MRP will be provided to the PI(s) 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 FY20 funds are anticipated to be made no later than September 30, 2021. 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.B.

***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**

An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed 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 2, Section B, for general information on organization or PI changes.

### **II.F.1.b. Pre-Award Meeting**

### **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 [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.

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 \$10,000,000 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](mailto: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](mailto: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 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

### **II.H.2. Administrative Actions**

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

#### **II.H.2.a. Rejection**

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

- Preproposal Narrative exceeds page limit.

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- 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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

#### **II.H.2.c. Withdrawal**

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

- An FY20 MRP 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 FY20 MRP Programmatic Panel members can be found at <https://cdmrp.army.mil/mrp/panels/panels20>.*
- 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 FY20, 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 invited application proposes a different research project than that described in the pre-application.
- Preliminary data are not included.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The Partnering PI does not meet the eligibility criteria.
- The pre-application or application does not address at least one of the FY20 MRP Focus Areas in [Section II.A.1](#).
- The pre-application or application does not address FY20 MRP Challenge Statement.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline, if applicable.

#### **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	Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for Federal Assistance ( <b>extramural submissions only</b> )	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )	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"		
	Source and Quality Assessment of Samples: Upload as Attachment 6 with file name "SQASamples.pdf"		
	Letter of Resource Support: Upload as Attachment 7 with file name "Resource.pdf"		
	Collaborative Statement: Upload as Attachment 8 with file name "Collaborative.pdf"		
	Research Outcomes Plan: Upload as Attachment 9 with file name "Outcomes.pdf"		
	Impact Statement: Upload as Attachment 10 with file name "Impact.pdf"		
	Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf" if applicable		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
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 ( <b>extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget ( <b>intramural submissions only</b> )	Complete the Suggested DoD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	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
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
MRP	Melanoma Research Program
NIH	National Institutes of Health
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
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