I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Orthotics and Prosthetics Outcomes Research Program

Clinical Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-OPORP-CRA

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), July 15, 2020
- Application Submission Deadline: 11:59 p.m. ET, July 29, 2020
- End of Application Verification Period: 5:00 p.m. ET, August 3, 2020
- Peer Review: September 2020
- Programmatic Review: December 2020

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) Orthotics and Prosthetics Outcomes Research Program (OPORP) 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 OPORP was established by Congress in FY14 to enhance the lives of Service members, Veterans, and others recovering from traumatic neuromusculoskeletal injury by means of improving the outcomes of orthotic and prosthetic device implementation. This includes improving the ability to carry out daily activities, enhancing work productivity, and increasing the possibility of returning to duty. Annual appropriations for the OPORP from FY14 through FY19 were $10 million (M) each year, and totaled $60M. The FY20 appropriation is $15M.

The vision of the OPORP is the highest possible quality of life for our injured Warfighters through the advancement of knowledge in orthotics- and prosthetics-related research. The OPORP supports research on outcomes-based best practices through analysis of prosthetic and/or orthotic device options that are currently available, and not on the development of a new technology or the improvement of an existing technology. Outcomes-focused research supported by the program is intended for the purpose of advancing orthotic and prosthetic device prescription, treatment, rehabilitation, and prevention of secondary health effects for patients, clinicians, caregivers, and policymakers.

Applications involving multidisciplinary collaborations among academia, industry, patient advocacy, the military Services, the Department of Veterans Affairs (VA), and/or other Federal Government agencies are highly encouraged.

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

II.A.1. FY20 OPORP Focus Areas

Applications to the FY20 OPORP Clinical Research Award (CRA) must address at least one of the Focus Areas listed below. Selection of the appropriate primary Focus Area is the responsibility of the applicant. This mechanism supports novel and innovative orthotics and prosthetics outcomes research, including development and employment of new approaches and tools for measuring outcomes. Research that involves developing or enhancing orthotic or prosthetic devices is not allowed.
Orthoses or Prostheses Form: Optimize patient outcomes through the analysis and characterization of variables related to the form of currently available clinical options such as device size, shape, material, and/or configurations.

Orthoses or Prostheses Fit: Optimize patient outcomes related to human-device interface through the analysis of variables in currently available clinical options that facilitate fit-related metrics such as comfort and/or usability.

Orthoses or Prostheses Function: Optimize patient outcomes through the analysis of variables related to currently available device function such as device control, sensors, and passive or active response with respect to activities of daily living and other real-world activities.

II.A.2. Award History

The OPORP CRA mechanism was first offered in FY18. Since then, 40 CRA applications have been received, and 11 have been recommended for funding.

II.B. Award Information

The FY20 OPORP CRA is intended to support clinical research that evaluates orthoses and/or prostheses using patient-centric outcomes relevant to Service members, Veterans, and other individuals with limb loss and/or limb impairment. Research supported by this mechanism is intended to generate clinically useful evidence with potential to enhance and optimize patient outcomes.

The FY20 OPORP CRA offers funding for two Funding Levels (Refer to Section II.D.5, Funding Restrictions). Only one Funding Level category may be chosen per application and the choice of application category is at the discretion of the applicant. The following are generalized descriptions of the scope of research appropriate for each Funding Level:

- **Funding Level 1** supports pilot and early-stage research studies that have the potential to make significant advancements toward clinical translation. Preliminary data are encouraged but not required for this Funding Level.

- **Funding Level 2** supports research that has the potential to make significant advancements toward clinical translation. Proposed projects may include large-scale studies that, if successful, will produce high-quality outcomes that provide strong support for evidence-based practice and/or have the potential to drive changes in clinical practice. Preliminary data and/or published data from the literature that are relevant to the orthotic and/or prosthetic device outcomes and support the rationale for the proposed research are required.

The FY20 OPORP CRA supports clinical research but **not** clinical trials. Supported clinical research may include (but is not limited to) methodologies and designs such as surveys, observational studies, or meta-analysis and systematic reviews that focus on outcomes related to the FY20 OPORP Focus Areas. An observational study is a type of clinical study in which individuals are observed or certain outcomes are measured, but no attempt is made to affect the outcome.
Clinical trials are not supported by this mechanism. Applicants seeking funding for a clinical trial should consider the FY20 OPORP Clinical Trial Award mechanism (Funding Opportunity: W81XWH-20-OPORP-CTA). 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. For more information, a Human Subject Resource Document is provided at https://ebrap.org/eBRAP/public/Program.htm.

Preclinical studies using animals are not supported by this Program Announcement.

Preliminary Data: Preliminary data are allowed but not required for Funding Level 1 applications. Applications for Funding Level 2 must include preliminary data and/or published data from the literature that are relevant to orthotic and/or prosthetic device outcomes and support the rationale for the proposed research project.

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 Department of Defense (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 total costs budgeted for the entire period of performance for an FY20 OPORP Clinical Research Award will not exceed $350,000 (Funding Level 1) or $2M (Funding Level 2). 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 $4.7M to fund approximately two CRA Funding Level 1 and two CRA Funding Level 2 Award applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this 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 proposal 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.

**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.

**DoD and VA Collaboration and Alignment Encouraged:** Relevance to the healthcare needs of the Armed Forces, their family members, and/or the Veteran population is a key feature of this award. Therefore, PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with the DoD or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

**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

Independent investigators at all academic levels (or equivalent) may be named by the organization as PI on the application.

There are no limitations on the number of applications for which an investigator may be named as a PI.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

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

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

Intramural DoD Submission:

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

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

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

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

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

Submission is a two-step process requiring both pre-application (eBRAP.org) and full application (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1, Full Application Guidelines).

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

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

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. Incorrect selection of extramural or intramural submission type will delay processing.
If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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

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

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

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

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

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.
FY20 OPORP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY20 OPORP Focus Area(s) under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

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

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

An invitation to submit a full application is **not** required

*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

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

Table 1. Full Application Submission Guidelines

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<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
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<tr>
<td><strong>Application Package Location</strong></td>
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<tr>
<td>Download application package components for W81XWH-20-OPORP-CRA 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.</td>
<td>Download application package components for W81XWH-20-OPORP-CRA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</td>
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<td><strong>Full Application Package Components</strong></td>
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<tr>
<td><strong>SF424 Research &amp; Related Application for Federal Assistance Form:</strong> Refer to the General Application Instructions, Section III.A.1, for detailed information.</td>
<td><strong>Tab 1 – Summary:</strong> Provide a summary of the application information.</td>
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<td><strong>Tab 2 – Application Contacts:</strong> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</td>
<td><strong>Tab 2 – Application Contacts:</strong> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</td>
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<td>Descriptions of each required file can be found under Full Application Submission Components:</td>
<td><strong>Tab 3 – Full Application Files:</strong> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</td>
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<td>• Attachments</td>
<td>• Attachments</td>
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<td>• Research &amp; Related Personal Data</td>
<td>• Key Personnel</td>
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<tr>
<td>• Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>• Budget</td>
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<td>• Research &amp; Related Budget</td>
<td>• Performance Sites</td>
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<td>• Project/Performance Site Location(s) Form</td>
<td><strong>Tab 4 – Application and Budget Data:</strong> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</td>
</tr>
<tr>
<td>• Research &amp; Related Subaward Budget Attachment(s) Form (if applicable)</td>
<td><strong>Tab 5 – Submit/Request Approval Full Application:</strong> After all components are uploaded and prior to the full application submission deadline, enter your password in the space</td>
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<tr>
<td><strong>Application Package Submission</strong></td>
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<tr>
<td><strong>Create a Grants.gov Workspace.</strong> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</td>
<td><strong>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</strong></td>
</tr>
<tr>
<td><strong>Submit a Grants.gov Workspace Package.</strong></td>
<td><strong>Tab 5 – Submit/Request Approval Full Application:</strong> After all components are uploaded and prior to the full application submission deadline, enter your password in the space</td>
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<tr>
<td>Extramural Submissions</td>
<td>Intramural DoD Submissions</td>
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<tr>
<td>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 <strong>at least 24-48 hours prior to the close date</strong> to allow time to correct any potential technical issues that may disrupt the application submission. <strong>Note:</strong> 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 prior to the application submission deadline. <strong>Do not password protect any files of the application package, including the Project Narrative.</strong></td>
<td>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. <strong>Do not password protect any files of the application package, including the Project Narrative.</strong></td>
</tr>
</tbody>
</table>

### Application Verification Period

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 **with the exception of the Project Narrative and Research & Related Budget Form.**

After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified **with the exception of the Project Narrative and Research & Related Budget Form.** 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.

### Further Information

**Tracking a Grants.gov Workspace Package.** After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.
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 (see below for page limit, which varies by Funding Level):** 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.

  **Page Limit:** Page limits for the Project Narrative are correlated with the application’s Funding Level:

  - **Funding Level 1:** Six-page limit
  - **Funding Level 2:** Fifteen-page limit

  Describe the proposed project in detail using the outline below.

  - **Background:** State the relevance of the proposed research and applicability of the proposed anticipated findings to at least one of the FY20 OPORP Focus Areas. Present the scientific rationale behind the proposed work. Cite relevant literature and pilot or preliminary data (if applicable). Provide a summary of relevant ongoing or prior clinical and preclinical work and distinguish how the proposed study differs
from other relevant or recently completed research. Include a discussion of any current clinical use of the orthotic or prosthetic device under investigation and/or details of its study in clinical research for other indications (if applicable).

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be achieved.

- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this award.

- **Research Strategy:** Describe the study design, methods, models, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility.
  - Explain how this research strategy will meet the research goals and milestones.
  - Address potential problems that may arise and present alternative methods and approaches.
  - Provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach.
  - Describe how data will be reported and how it will be assured that the documentation will support a potential regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.
  - *For applications submitted to Funding Level 1:* Describe the statistical plan including power analysis, as appropriate, for the proposed research.
  - *For applications submitted to Funding Level 2:* Describe the statistical model and data analysis plan with respect to the study objective. For studies enrolling human subjects, specify the approximate number of subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objective of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **For research involving human subjects:**
  - Identify the orthotic or prosthetic device to be studied (if applicable) and describe the outcomes being studied.
  - Briefly describe the study population and provide metrics on available participants at each research site.
- Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be evaluated.

- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).

- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- **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. Copies of published manuscripts in excess of five total 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.

- **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.

- **Quad Chart:** Provide a quad chart for the project using the template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm).

  - **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 how the proposed research addresses one or more of the FY20 OPORP Focus Areas. Present the ideas and reasoning behind the proposed work.
– **Objective/Hypothesis:** State the objective to be reached or the hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

– **Specific Aims:** State the specific aims of the study.

– **Study Design:** Briefly describe the study design, including appropriate controls.

– **Impact and Relevance to Military Health:** Briefly describe the immediate and/or long-term impact of the proposed research on the health and well-being of Service members and Veterans with limb loss and/or limb impairment as well as their family members, their caregivers, and/or the American public.

○ **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.*

– Describe the objectives and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.

– Describe the ultimate applicability and potential impact of the research.

– Describe the types of patients that will be helped by the research and how it will help them. Include currently available statistics for the related injury/condition.

– Describe potential clinical applications, benefits, and risks.

– Describe the projected timeline to achieve the expected patient-related outcome.

– Describe how the proposed project will benefit Service members and Veterans with limb loss and/or limb impairment as well as their family members, their caregivers, and/or the American public.

○ **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](https://ebrap.org/eBRAP/public/Program.htm)). For the Clinical Research Award mechanism, use the SOW format example titled, “SOW 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 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.

– If applicable, indicate timelines required for regulatory approvals relevant to human subjects research by Government agencies (e.g., USAMRDC ORP).

○ Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”. Describe how the short-term and long-term outcome(s) of the proposed research, if successful, will advance the field of orthotics and prosthetics outcomes research, impact the standard of care, contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care, improve the quality of life, and/or otherwise impact the lives and health of individuals with limb loss and/or limb impairment. If applicable, describe the proposed research in the context of existing clinical practice guidelines (CPGs) and describe the potential impact of the anticipated outcome(s) of this work on those guidelines. Address the impact on at least one of the FY20 OPORP Focus Areas. This should be written with a broad audience in mind, including readers without a background in science or medicine.

○ Attachment 7: Relevance to Military Health Statement (one-page limit): Upload as “MilRel.pdf”. Demonstrate how the proposed research project is responsive to the healthcare needs and quality of life of Service members and Veterans with limb loss and/or impairment and/or to their families and caregivers. If active duty military, Veteran, or military family population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the results will be relevant to the targeted population.

○ Attachment 8: Transition Plan (two-page limit): Upload as “Transition.pdf”. Describe the methods and strategies proposed to advance the anticipated research outcomes to the next phase of research or delivery to the military and civilian market after successful completion of the award. The Transition Plan should include the components listed below.

– Details of the strategy, schedule, and milestones for transition to the next phase of development, implementation, and/or commercialization (e.g., partners, next-phase clinical studies, incorporation into clinical practice, funding opportunities to be pursued if applicable).
For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of CPGs and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. Describe how the work proposed, if successful, will be translated to stakeholders (e.g., researchers, clinicians, hospitals, third-party payers, patients) in order to facilitate the greatest possible and most expeditious impact. (A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.

If applicable, a risk analysis for cost, schedule, manufacturability, and sustainability.

Attachment 9: Human Subject Recruitment and Safety Procedures (if applicable; required for all studies recruiting human subjects; no page limit): Upload as “HumSubProc.pdf”. The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical research (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Identify ongoing clinical research that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. For clinical studies proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.

Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.
**Inclusion of Women and Minorities in Study.** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical research.

- **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and healthcare provider identification).
  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the study.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
  - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual’s Legally Authorized Representative (LAR) to be obtained prior to the human subject’s participation in the study. State law defines who may act as the LAR. The local IRB of record...
should be consulted for guidance regarding who can serve as LAR for research at the study site.  

**Note:** In compliance with 10 USC 980 (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial. If applicable, refer to the General Application Instructions, Appendix 1, for more information.

- **Assent.** If minors or other populations that cannot provide informed consent are included in the proposed clinical research, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry.  

  **Note:** Some screening procedures may require a separate consent or a two-stage consent process.

- **Risks/Benefits Assessment:**

  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical research. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

  - **Risk management and emergency response:**

    ✓ Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.

    ✓ Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.

    ✓ Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).

    ✓ Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 10: Data Management (if applicable; required for all studies recruiting human subjects; no page limit):** Upload as “Data_Manage.pdf”. The Data Management attachment should include the components listed below.
  - **Data Management:** Describe all methods used for data collection, including the following:
    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
    - **Confidentiality:**
      - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
      - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
      - Address requirements for reporting sensitive information to state or local authorities.
    - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process.
    - **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
    - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.
Laboratory Evaluations:

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).

- **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- **Laboratories performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

○ **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 (six-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

- Key Personnel Biographical Sketches (six-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.

**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.

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 FY20 OPORP CRA offers two Funding Levels. It is the responsibility of the applicant to select the Funding Level that is most appropriate for the proposed research project.

For Funding Level 1 Applications:

The maximum period of performance is 2 years.

The anticipated total (direct + indirect) costs budgeted for the entire period of performance will not exceed $350,000. 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 $350,000 total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

For Funding Level 2 Applications:

The maximum period of performance is 4 years.

The anticipated total (direct + indirect) costs budgeted for the entire period of performance will not exceed $2M. 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 $2M total costs or using an indirect cost rate exceeding the organization’s negotiated rate.

All funding amounts requested should be well-justified and appropriate for the scope of work proposed. Applications for projects requiring levels of funding less than $350,000 total costs and less than $2M total costs may be submitted to Funding Level 1 and Funding Level 2, respectively.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 2 years for Funding Level 1 applications, or 4 years for Funding Level 2 applications.

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

- Travel costs for the PI to present project information or disseminate project results at one DoD-sponsored meeting (e.g., Military Health System Research Symposium) during the period of performance in Year 2 or beyond should be requested. For planning purposes, it should be assumed that the meeting will be held in the Central Florida region. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for travel including:

- Travel in support of multidisciplinary collaborations.

- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information and outcomes of the FY20 OPORP CRA.

Must not be requested for:

- Animal research costs

- Clinical trial costs

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**
  - How well the preliminary data (if applicable) and scientific rationale support the research project.
  - How well the hypothesis or objective, specific aims, study design, methods, models, and analyses are developed and integrated into the project.
  - Whether the research goals and milestones are achievable in the proposed schedule.
  - How well the application acknowledges potential problems and addresses alternative methods and approaches.
  - How well the application outlines a plan for management and sharing of research data as appropriate for the type of study.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - For research involving human subjects:
    - How well the application describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
    - How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and the process for obtaining informed consent.
  - *For applications submitted to Funding Level 1*: To what degree the statistical plan including power analysis, as appropriate, is suitable for the research proposed.
• **Impact**
  
  ○ To what extent the short-term and long-term outcome(s) of the proposed research, if successful, will advance the field of orthotics and prosthetics outcomes research, impact the standard of care, contribute to the development or validation of evidence-based policy or guidelines for patient evaluation and care, improve the quality of life, and/or otherwise impact the lives and health of individuals with limb loss and/or limb impairment.
  
  ○ If applicable, to what extent the anticipated outcome(s) of the proposed work may impact existing CPGs.
  
  ○ How well the proposed research project demonstrates potential for impact with respect to at least one of the [FY20 OPORP Focus Areas](#).

• **Statistical and Data Analysis Plan (Funding Level 2 only)**
  
  ○ To what degree the statistical model and data analysis plan are suitable with respect to the study objective.
  
  ○ How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  
  ○ If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.

• **Personnel**
  
  ○ To what extent the backgrounds and expertise of the PI and key personnel are appropriate to accomplish the proposed research project.
  
  ○ To what extent the levels of effort by the PI and key personnel are appropriate to ensure the success of this project.
  
  ○ How well the PI’s record of accomplishments demonstrates their ability to accomplish the proposed research project.

• **Transition Plan**
  
  ○ Whether the strategy, schedule, and milestones for transition to the next phase of development, implementation, and/or commercialization (e.g., partners, next-phase clinical studies, incorporation into clinical practice, funding opportunities to be pursued if applicable) are realistic and reasonable.
  
  ○ For Knowledge Products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of CPGs and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and
applications are achievable. Whether the plan for translation of the anticipated outcome(s) to stakeholders (e.g., researchers, clinicians, hospitals, third-party payers, patients) in order to facilitate the greatest possible and most expeditious impact is appropriate and achievable.

○ How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and/or commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement.

○ If applicable, whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

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

- **Environment**
  
  ○ To what degree the scientific environment and the accessibility of institutional/organizational resources support the proposed research.

  ○ Whether the quality and extent of institutional support are appropriate for the proposed project.

- **Budget**
  
  ○ Whether the total costs exceed the allowable total costs as published in the Program Announcement.

  ○ Whether the budget is appropriate for the proposed research.

- **Application Presentation**
  
  ○ To what extent the writing, clarity, and presentation of the application components influence the review.

**II.E.1.b. Programmatic Review**

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

• Relevance to the mission of the DHP and FY20 OPORP, as evidenced by the following:
  ○ Adherence to the intent of the award mechanism
  ○ Program portfolio composition
  ○ Relevance to military health
  ○ Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is programmatic review, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found at [https://cdmrp.army.mil/about/2tierRevProcess](https://cdmrp.army.mil/about/2tierRevProcess). An information paper describing the funding recommendations and review process for the award mechanisms for the OPORP will be provided to the PI and posted on the CDMRP website.

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

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).
An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

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

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

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with 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

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

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.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.

Annual quad charts as well as a final quad chart 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

II.G.2. Grants.gov Contact Center

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

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

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

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

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

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY20 OPORP 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 OPORP Programmatic Panel members can be found at https://cdmrp.army.mil/oporp/panels/porpppanel20.
- 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.

Animal studies are proposed.

A clinical trial is proposed.

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

<table>
<thead>
<tr>
<th>Application Components</th>
<th>Action</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 Research &amp; Related Application for Federal Assistance <em>(extramural submissions only)</em></td>
<td>Complete form as instructed</td>
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<tr>
<td>Summary (Tab 1) and Application Contacts (Tab 2) <em>(intramural submissions only)</em></td>
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<tr>
<td>Attachments</td>
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<tr>
<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf”</td>
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<tr>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf”</td>
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<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf”</td>
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<tr>
<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf”</td>
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<tr>
<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf”</td>
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<td>Impact Statement: Upload as Attachment 6 with file name “Impact.pdf”</td>
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<tr>
<td>Relevance to Military Health Statement: Upload as Attachment 7 with file name “MilRel.pdf”</td>
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<tr>
<td>Transition Plan: Upload as Attachment 8 with file name “Transition.pdf”</td>
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<tr>
<td>Human Subject Recruitment and Safety Procedures: Upload as Attachment 9 with file name “HumSubProc.pdf” if applicable</td>
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<tr>
<td>Data Management: Upload as Attachment 10 with file name “Data_Manage.pdf” if applicable</td>
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<tr>
<td>Representations (extramural submissions only): Upload as Attachment 11 with file name “RequiredReps.pdf” if applicable</td>
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<tr>
<td>Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 12 with file name “MFBudget.pdf” if applicable</td>
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</tr>
<tr>
<td>Research &amp; Related Personal Data</td>
<td>Complete form as instructed</td>
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<tr>
<td>Application Components</td>
<td>Action</td>
<td>Completed</td>
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<tr>
<td>-----------------------------------------------------</td>
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<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field</td>
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</tr>
<tr>
<td></td>
<td>Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field</td>
<td></td>
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<tr>
<td>Research &amp; Related Budget (extramural submissions only)</td>
<td>Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field</td>
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<tr>
<td>Budget (intramural submissions only)</td>
<td>Suggested DoD Military Budget Format, including justification</td>
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<tr>
<td>Project/Performance Site Location(s) Form</td>
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<tr>
<td>Research &amp; Related Subaward Budget Attachment(s) Form, if applicable</td>
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### APPENDIX 1: ACRONYM LIST

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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</thead>
<tbody>
<tr>
<td>ACOS/R&amp;D</td>
<td>Associate Chief of Staff for Research and Development</td>
</tr>
<tr>
<td>CDMRP</td>
<td>Congressionally Directed Medical Research Programs</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CPGs</td>
<td>Clinical Practice Guidelines</td>
</tr>
<tr>
<td>DHA</td>
<td>Defense Health Agency</td>
</tr>
<tr>
<td>DHP</td>
<td>Defense Health Program</td>
</tr>
<tr>
<td>DoD</td>
<td>Department of Defense</td>
</tr>
<tr>
<td>DoDGARs</td>
<td>Department of Defense Grant and Agreement Regulations</td>
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<tr>
<td>DUNS</td>
<td>Data Universal Numbering System</td>
</tr>
<tr>
<td>eBRAP</td>
<td>Electronic Biomedical Research Application Portal</td>
</tr>
<tr>
<td>EC</td>
<td>Ethics Committee</td>
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<tr>
<td>ET</td>
<td>Eastern Time</td>
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<tr>
<td>FAD</td>
<td>Funding Authorization Document</td>
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<tr>
<td>FAPIIS</td>
<td>Federal Awardee Performance and Integrity Information System</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>FY</td>
<td>Fiscal Year</td>
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<tr>
<td>HRPO</td>
<td>Human Research Protection Office</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>LAR</td>
<td>Legally Authorized Representative</td>
</tr>
<tr>
<td>LOI</td>
<td>Letter of Intent</td>
</tr>
<tr>
<td>M</td>
<td>Million</td>
</tr>
<tr>
<td>MIPR</td>
<td>Military Interdepartmental Purchase Request</td>
</tr>
<tr>
<td>OASD(HA)</td>
<td>Office of the Assistant Secretary of Defense for Health Affairs</td>
</tr>
<tr>
<td>OPORP</td>
<td>Orthotics and Prosthetics Outcomes Research Program</td>
</tr>
<tr>
<td>ORCID</td>
<td>Open Researcher and Contributor ID, Inc.</td>
</tr>
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<td>ORP</td>
<td>Office of Research Protections</td>
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<tr>
<td>PI</td>
<td>Principal Investigator</td>
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<tr>
<td>RDT&amp;E</td>
<td>Research, Development, Test, and Evaluation</td>
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<tr>
<td>SAM</td>
<td>System for Award Management</td>
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<tr>
<td>SOW</td>
<td>Statement of Work</td>
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<tr>
<td>STEM</td>
<td>Science, Technology, Engineering, and/or Mathematics</td>
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<tr>
<td>UEI</td>
<td>Unique Entity Identifier</td>
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<tr>
<td>USAMRAA</td>
<td>U.S. Army Medical Research Acquisition Activity</td>
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<td>USAMRDC</td>
<td>U.S. Army Medical Research and Development Command</td>
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<td>USC</td>
<td>United States Code</td>
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<tr>
<td>VA</td>
<td>Department of Veterans Affairs</td>
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</table>
APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD and/or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration.

Air Force Office of Scientific Research  
https://www.wpafb.af.mil/afrl/afosr/

Air Force Research Laboratory  
https://www.wpafb.af.mil/afrl/

Armed Forces Radiobiology Research Institute  
https://www.usuhs.edu/afri/

Clinical and Rehabilitative Medicine Research Program  
https://crmrp.amedd.army.mil/

Combat Casualty Care Research Program  
https://ccc.amedd.army.mil

Congressionally Directed Medical Research Programs  
https://cdmrp.amedd.army.mil

Defense Advanced Research Projects Agency  
https://www.darpa.mil/

Defense Health Agency  
https://health.mil/dha

Defense Technical Information Center  
https://www.dtic.mil

Defense Threat Reduction Agency  
https://www.dtra.mil/

Military Health System Research Symposium  
https://mhsrs.amedd.army.mil/SitePages/Home.aspx

Military Infectious Diseases Research Program  
https://midrp.amedd.army.mil

Military Operational Medicine Research Program  
https://momrp.amedd.army.mil

Naval Health Research Center  
https://www.med.navy.mil/sites/nmrc/nhrc/Pages/default.aspx

Navy Bureau of Medicine  
https://www.med.navy.mil/

Naval Medical Research Center  
https://www.med.navy.mil/sites/nmrc

Navy and Marine Corps Public Health Center  
https://www.med.navy.mil/sites/nmephc/Pages/Home.aspx

Office of Naval Research  
https://www.onr.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics  
https://www.acq.osd.mil/

Telemedicine and Advanced Technology Research Center  
https://www.tatrc.org/

Uniformed Services University of the Health Sciences  
https://www.usuhs.edu/research

U.S. Air Force 59th Medical Wing  
https://www.59mdw.af.mil/

U.S. Army Aeromedical Research Laboratory  
https://www.usaarl.army.mil
U.S. Army Institute of Surgical Research
https://usaisr.amedd.army.mil/

U.S. Army Research Institute of Environmental Medicine
https://www.usariem.army.mil

U.S. Army Medical Research Institute of Infectious Diseases
https://www.usamriid.army.mil

U.S. Army Medical Research and Development Command
https://mrdc.amedd.army.mil/

U.S. Army Research Laboratory
https://www.arl.army.mil

U.S. Army Combat Capabilities Development Command
https://www.army.mil/ccdc

U.S. Army Sharp, Ready & Resilient Directorate
https://readyandresilient.army.mil/

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil

U.S. Department of Veterans Affairs, Office of Research and Development
https://www.research.va.gov

U.S. Naval Research Laboratory
https://www.nrl.navy.mil/

Walter Reed Army Institute of Research
https://www.wrair.army.mil/