I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Tick-Borne Disease Research Program

Career Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-TBDRP-CDA

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), May 22, 2019

○ **Application Submission Deadline:** 11:59 p.m. ET, August 22, 2019

○ **End of Application Verification Period:** 5:00 p.m. ET, August 27, 2019

○ **Peer Review:** November 2019

○ **Programmatic Review:** January 2020

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190218. 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."

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2019 (FY19) Tick-Borne Disease Research Program (TBDRP) 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 TBDRP was initiated in 2016 to support innovative and impactful research that address fundamental issues and gaps in knowledge of tick-borne diseases. Appropriations for the TBDRP from FY16 through FY18 totaled $15 million (M). The FY19 appropriation is $5M.

The TBDRP's vision is to prevent the occurrence, better diagnose, and resolve or minimize the impact of Lyme disease and other tick-borne illnesses, with emphasis on burden of disease. The TBDRP's mission is to support research to understand the pathogenesis of Lyme disease and other tick-borne illnesses, to deliver innovative solutions to prevent, better diagnose, and treat their manifestations for the benefit of military Service members and the American public, and to disseminate this knowledge.

II.A.1. FY19 TBDRP Focus Areas

To meet the intent of the award mechanism, applications submitted to the FY19 TBDRP _**must**_ address at least one of the following specific Focus Areas in Lyme disease and other tick-borne diseases with emphasis on reducing public health burden. ***Applications focused on tick-borne diseases prevalent in the US and/or involving understudied patient populations are encouraged, but not required.***

- **Diagnosis**

  - Accurate diagnostics and biomarkers for Lyme disease and co-infections and/or other tick-borne diseases

  - Diagnostic biomarkers for Lyme disease that distinguish between active infection and previous exposure, and/or monitor response to treatment

- **Pathogenesis**

  - Understanding pathogenic mechanisms, including immune protection, for Lyme disease, other tick-borne diseases, and/or co-infections

- Understanding the complex biology of Lyme borrelia in the host (beyond in vitro studies), including its survival, evasion of the host immune system, and subversion of the effectiveness of antibiotics

- Understanding underlying mechanisms of persistent symptoms associated with Lyme disease

- **Treatment**

  - Antibiotic combinations and/or therapeutic options for treating acute and persistent illness

- **Prevention**

  - Safe and effective human vaccines for tick-borne diseases

  - Identification, validation, and/or improvement of tick-targeted prevention and control interventions

  - Understanding the ecology of understudied tick-borne disease vectors and reservoirs with emphasis on how it relates to human risk

II.A.2. Award History

The TBDRP Career Development Award mechanism was first offered in FY18. Since then, six Career Development Award full applications have been received, and two have been recommended for funding.

II.B. Award Information

The **FY19 TBDRP Career Development Award** supports independent, early-career investigators in their efforts to conduct impactful research with the mentorship of an experienced tick-borne diseases researcher (i.e., the Mentor), thus providing an opportunity to obtain the funding, guidance, and experience necessary for productive, independent careers at the forefront of tick-borne diseases research. This award supports impactful research projects with an emphasis on discovery that may be translational in nature, but are not clinical trials. Under this award mechanism, the early-career investigator is considered the Principal Investigator (PI), and the application should focus on the PI's research and career development. It should be clear that the proposed research is intellectually designed by the PI and not a product of the Mentor. ***Preliminary data are not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.***

The following are key aspects of the FY19 TBDRP Career Development Award:

- **Principal Investigator:** The PI must be an early-career research scientist or physician scientist within 10 years of completion of his/her terminal degree (excluding time spent in residency or on family medical leave). The PI's record of accomplishments and the proposed research will be evaluated regarding his/her potential for contributing to the field of tick-

borne diseases research. Because career development is the focus of this award, the PI's institution must demonstrate a commitment to the PI through a minimum of 75% protected time for tick-borne diseases research, although more protected time is highly desirable.

- **Mentorship:** The Mentor must be an experienced tick-borne diseases researcher as demonstrated by a proven record of funding and publications in tick-borne diseases research. The Mentor must hold a position at or above the level of an Associate Professor (or equivalent). In addition, the Mentor must demonstrate a commitment to developing the PI's career in tick-borne diseases research. The Mentor and PI may be at different organizations.

- **Career Development Plan**: A career development plan is required and should be prepared by the PI with appropriate guidance from the Mentor. A clearly articulated strategy for acquiring the necessary skills, competence, and expertise to establish a career at the forefront of tick-borne diseases research should be included. The plan should outline how the PI will gain experience in tick-borne diseases research.

To leverage existing resources and maximize statistical power, Lyme and other tick-borne disease biorepositories and databases are important resources to consider if retrospectively collected human anatomical substances or correlated data are critical to the proposed studies. Investigators are strongly encouraged to incorporate the following components into their study design where appropriate: authentication of proposed cell lines; statistical rigor of *in vitro* cellular studies and preclinical animal experiments; and validation in well-pedigreed cohorts of uniformly documented patients. Studies utilizing data derived from large patient studies that include long-term health records, biospecimen repositories, and pre-existing research, and/or studies that apply state-of-the art genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged.

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

The anticipated direct costs budgeted for the entire period of performance for an FY19 TBDRP Career Development Award will not exceed **$250,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The CDMRP expects to allot approximately $0.8M to fund approximately two Career Development Award applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

Awards will be made no later than September 30, 2020. For additional information refer to Section II.F.1, Federal Award Notices.

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). 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.

An assistance agreement (grant or cooperative 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. 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 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.

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 Materiel Command (USAMRMC) 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. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in Attachment 5: Statement of Work (SOW). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. 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.

New FY19 definition: A clinical trial is 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.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this Program Announcement.

Note: Applications proposing research involving human subjects and/or human anatomical substances should be submitted under the Human Subjects/Sample Acquisition Option.

Use of DoD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active duty military patient populations and/or DoD 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. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including 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. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should 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.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at https://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." *Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Application Instructions, Appendix 1, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

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, other 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.

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

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator and Mentor

- **Principal Investigator**

  ○ The PI must be an early-career researcher or physician scientist within 10 years of completion of his/her terminal degree at the time of application submission deadline (excluding time spent in residency or on family medical leave) and exhibit a strong desire to pursue a career in tick-borne diseases research. Time spent as a postdoctoral fellow is *not* excluded.

  ○ Institutional commitment to the PI's independent career should be demonstrated, including a confirmation of the laboratory space.

- **Mentor**

  ○ The Mentor must hold a position at or above the level of an Associate Professor (or equivalent).

  ○ The Mentor must be an experienced researcher as demonstrated by a proven record of funding and publications in tick-borne diseases research. The Mentor must demonstrate a commitment to developing the PI's career in tick-borne diseases research.

The PI and the Mentor do not need to be located within the same organization.

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.

Each investigator may be named on only one FY19 TBDRP Career Development Award application as PI.

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: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

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.

Extramural Submissions:

- 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 Submissions:

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

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

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*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

Full Application Submission: Full applications must be submitted through the online portals as described below.

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from

extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

Intramural DoD Organization Submissions: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to 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. 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. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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 PIs and Mentors 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 PI 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.

When starting the pre-application, PIs should ensure that they have selected the appropriate application category and option (if applicable):

- Career Development Award; **or**

- Career Development Award – Human Subjects/Sample Acquisition Option

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. Note that the codes have recently been revised. 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.

  FY19 TBDRP 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 COI 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 FY19 TBDRP 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

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

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

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

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-19-TBDRP-CDA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-TBDRP-CDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email.

Extramural Submissions	Intramural DoD Submissions
to correct any potential technical issues that may disrupt the application submission. **Note:** 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.	
[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.

Both Extramural and Intramural Organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. 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.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

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

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

  ○ **Attachment 1: Project Narrative (eight-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below.

    – **Principal Investigator:** Describe the PI's potential for a career at the forefront of tick-borne diseases research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as a tick-borne diseases researcher and/or clinician and how the proposed research experience will advance his/her career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research.

    – **Mentor:** Describe the qualifications of the Mentor, including record of research accomplishments, publications, patents, and funding in tick-borne diseases research.

Describe the Mentor's track record for mentoring early-career investigators. If the Mentor and the PI are located within different organizations, describe how appropriate direction and oversight will be accomplished.

– **Research:**

▪ Background: Describe the problem, question, or knowledge gap related to at least one of the FY19 TBDRP Focus Areas to be addressed by the proposed research. Present the ideas and reasoning behind the proposed research. Describe the PI's and Mentor's previous experience most pertinent to the proposed research. Include relevant literature citations and preliminary data, if applicable, that led to the development of the proposed study to support the study's feasibility. Although not required, any preliminary data provided should be from the laboratory of the PI, Mentor, or member(s) of the collaborating team.

▪ Hypothesis/Objectives: State the hypothesis/study questions and overall objective(s) to be reached.

▪ Specific Aims: Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.

▪ Strategy: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of feasibility. Clearly describe how data will be collected, handled, and analyzed in a manner that is consistent with the study objectives.

▪ Address potential problem areas and present alternative approaches to mitigate these problems.

▪ If animals or human subjects/samples will be used, provide a statistical plan and sample size estimate for each study arm and the method by which it was derived, including power analysis calculations to demonstrate that the sample size is appropriate to meet the objectives of the study.

▪ If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. If retrospectively collected human biological samples or correlated data from biorepositories or databases will be used, describe how those samples or data are representative of well-pedigreed cohorts of uniformly documented patients. Further details of research involving human subjects or human biological substances will be required in Attachment 11, as applicable. ***This award cannot be used to conduct clinical trials.***

▪ If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen and their relevance to human biology. If cell line studies are proposed, include information about authentication of proposed cell lines. Describe the statistical rigor of *in vitro* cellular studies and preclinical animal experiments. If animal studies are proposed, describe how they will be

conducted in accordance with the ARRIVE guidelines
(https://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf).

- ▪ Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- – References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- – List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

- – Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- – Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- – Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. **Additionally, the letter(s) must demonstrate a commitment to allow at least a 75% effort on tick-borne diseases research projects by the PI.** 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 ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

○ **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

  - Personnel: Describe the PI's career goals and his/her potential for a career at the forefront of tick-borne diseases research. Describe the Mentor's background and experience in tick-borne diseases research.

- Career Development: Describe how the award will provide the PI with the opportunity to advance an independent career at the forefront of tick-borne diseases research.

- Research:

  - Background: Present the ideas and reasoning behind the proposed work.

  - Hypothesis/Objective: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the hypothesis/objective.

  - Specific Aims: State the specific aims of the study.

  - Study Design: Briefly describe the study design including appropriate controls.

  - Relevance: State the FY19 TBDRP Focus Area(s) that the project addresses. Describe the public health burden of the disease that the study will address, including study relevance to the healthcare needs and welfare of military Service members and 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.

Do not duplicate the technical abstract. Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. Lay abstracts should be written using the outline below.

- Describe the rationale, scientific objective, and aims for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine.***

  - State the FY19 TBDRP Focus Area(s) the project addresses.

- Describe the PI's career goals in tick-borne diseases research.

  - How will the award advance the PI's career in tick-borne diseases research?

  - How does the research and career development plan support the PI in attaining these goals?

- Describe the ultimate applicability of the research.

  - What is the project's potential impact on reducing the public health burden, including the potential effect of the proposed research on the health and welfare of military Service members and the American public?

  - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.

  - What is the projected time it may take to achieve a patient-related outcome?

  - What are the likely contributions of this study to advancing the field of tick-borne diseases research or patient care?

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Career Development 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 (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

  - Identify cell line(s) and commercial or organizational source(s) to be used.

  - If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the FDA or other Government agency.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Explain in detail how the proposed project addresses a critical problem in Lyme disease and/or other tick-borne diseases and will impact the FY19 TBDRP Focus Area(s) being addressed as follows:

- – *Describe the short-term impact:* Detail the anticipated short-term outcome(s)/ product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research.

  - – *Describe the long-term impact:* Explain the anticipated long-term gains from the proposed research, including the long-term anticipated advancements over current knowledge, technology, and/or practice.

- ○ **Attachment 7: Relevance Statement (one-page limit): Upload as "Relevance.pdf".** *The Relevance Statement will be evaluated by the FY19 TBDRP Programmatic Panel during the programmatic review only*.

  - – Public Health Burden: Describe the burden of illness for the disease(s) to be studied, including current evidence-based public health information on mortality, morbidity, and economic impact. Describe how the proposed research will reduce the burden of Lyme disease and/or other tick-borne illnesses and their effect on public health.

  - – Military Relevance: Describe how the proposed research is relevant to the healthcare needs and welfare of military Service members, Veterans, and their families in a way that is consistent with the program's goals.

- ○ **Attachment 8: Career Development Plan (one-page limit): Upload as "CareerDev.pdf".** The Career Development Plan attachment should be prepared by the PI with appropriate guidance from the Mentor.

  - – Clearly describe and outline the individualized career development plan.

  - – Highlight the unique features of this career development plan as it pertains specifically to tick-borne diseases research.

  - – Indicate specifically how the individualized career development plan will provide the PI with an opportunity to advance his/her independent career in tick-borne diseases research.

  - – Describe how the career development plan is supported by the research environment and mentorship provided by the proposed Mentor and others at the institution, including a description of ongoing tick-borne diseases research at the institution. Include information on collaborations with other investigators.

- ○ **Attachment 9: Eligibility Statement (one-page limit): Upload as "Eligibility.pdf".** Use the Eligibility Statement template (available for download on the Full Announcement page in Grants.gov and on the Funding Opportunities & Forms web page in eBRAP) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements, described in <u>Section II.C, Eligibility Information</u>, will be met by the application submission deadline.

- ○ **Attachment 10: Letter from Mentor (two-page limit): Upload as "MentorLetter.pdf".** Provide a signed letter from the Mentor indicating

recommendation, support, and planned interactions with the PI for the proposed work. The letter from the Mentor should detail individualized interaction between the Mentor and the PI for further career development. Include information on the Mentor's record of preparing early-career investigators for careers in tick-borne diseases research.

- ○ **Attachment 11: Human Subjects/Sample Acquisition and Safety Procedures (*required for applications submitted under the Human Subjects/Sample Acquisition Option*) (no page limit): Upload as "HumSubProc.pdf".** If the proposed study involves human subjects or human biological samples, the applicant is required to submit a summary describing the human research that will be conducted.

  – Describe the study population (i.e., nature, approximate number, and pertinent demographic characteristics), criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples.

  – Describe the informed consent process, and include relevant draft process documents and consent forms. It is recommended that informed consent allows for the use of samples for future studies.

  – Include a discussion of the screening procedures and risk/benefit considerations.

  – Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable.

  – Describe the types of specimens or data to be collected and evaluated, and include information about specimen storage and maintenance (i.e., location, duration, special handling conditions).

  – Include a description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.

  – Document the experience of the PI and/or key collaborators in recruiting human subjects/acquiring human samples for similar projects.

  – Address any potential barriers to accrual, including access to the proposed study samples/populations, and plans for addressing potential delays.

- ○ **Attachment 12: 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 13: DoD Military Budget Form(s), 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 the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page [(https://ebrap.org/eBRAP/public/Program.htm)](https://ebrap.org/eBRAP/public/Program.htm), 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)](https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

    - Key Personnel Biographical Sketches (six-page limit each): Upload as "Biosketch_LastName.pdf".

        – Include Mentor's biographical sketch.

    - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

        – Include Mentor's previous/current/pending support.

    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 DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (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.

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

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 retrieved files against the specific Program Announcement requirements, and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. 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 Budget Form cannot be changed after the application submission deadline.

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

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

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

II.D.5. Funding Restrictions

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **$250,000**. 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 **$250,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

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

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary

- Research supplies

- Research-related subject costs

- Clinical research costs (other than costs for clinical trials, which are not allowed)

- Support for multidisciplinary collaborations, including travel

- Travel costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to this scientific/technical meeting is to present project information or disseminate project results and attend workshops as designated in the Career Development Plan (Attachment 8) from the FY19 TBDRP Career Development Award.

Must not be requested for:

- Clinical trial costs

- Mentor salary

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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*.

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. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

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:

- **Principal Investigator**

  - Whether the PI meets the eligibility requirements.

  - To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of tick-borne diseases research.

  - To what extent the PI's record of accomplishments and letters of support demonstrate his/her potential for advancement as a productive, independent investigator in tick-borne diseases research.

- **Career Development Plan and Environment**

  - How well the PI has outlined a detailed, individualized career development plan that will effectively advance his/her independent career as a tick-borne diseases researcher.

  - To what degree the proposed career development plan (such as workshops, seminars, etc.) is appropriate and will prepare the PI for a successful independent career at the forefront of tick-borne diseases research.

  - Appropriateness of the levels of effort by the PI, Mentor, and other key personnel to ensure the success of this research effort.

  - To what extent unique features of the research environment are integrated into the career development plan, including potential collaborations, and how appropriate the features are to advance the independent career of the PI.

  - Whether there is a clear organizational commitment to allow protection of at least 75% of the PI's time for tick-borne diseases research.

  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

  - Whether the Mentor is an independent, established researcher in tick-borne diseases research as demonstrated by a record of publications, patents, and/or funding history.

  - To what degree the Mentor demonstrates a commitment to the PI's career development and research as demonstrated by planned interactions with the PI. If the Mentor and PI

are located at different institutions, whether plans for providing appropriate direction and oversight are outlined.

- ○ To what degree the Mentor's track record in mentoring early-career investigators indicates the potential for successful mentorship and development of the PI's independent career in tick-borne diseases research.

- ○ To what degree the research project is appropriate for advancing the PI's independent career at the forefront of tick-borne diseases research.

- **Impact**

  - ○ If successful, to what extent the proposed project will address a critical problem in Lyme disease and/or other tick-borne diseases and impact the FY19 TBDRP Focus Area(s) being addressed.

  - ○ If successful, to what extent the anticipated short-term or long-term research outcome(s)/products(s) (intellectual and/or tangible) will significantly advance current knowledge, technology, and/or practice, ultimately contributing to the field of Lyme disease and/or other tick-borne diseases research, patient care, and/or quality of life.

- **Research Strategy and Feasibility**

  - ○ How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if available), and inferential reasoning.

  - ○ How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.

  - ○ How well the PI acknowledges potential problems and addresses alternative approaches.

  - ○ If animals or human subjects/samples will be used, whether the application includes an appropriate statistical plan with power analysis to demonstrate appropriate sample size to meet study objectives.

  - ○ How well studies are designed to achieve reproducible and rigorous results.

  - ○ If cell lines or animals will be used, how well the proposed cell line(s) or animal model(s) are justified and how well the study (or studies) is designed to achieve the objectives, including the choice of endpoints/outcome measures to be used.

  - ○ If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- **Human Subjects/Sample Acquisition and Safety Procedures (*for applications submitted under the Human Subjects/Sample Acquisition Option*)**

  ○ If retrospectively collected human biological samples or correlated data from biorepositories or databases will be used, whether the samples or data are validated in well-pedigreed cohorts of uniformly documented patients

  ○ The degree to which the sample acquisition and/or human subjects recruitment, informed consent, screening, and retention processes are justified and appropriate to accomplish the proposed work.

  ○ Whether there is sufficient evidence provided to support availability of and access to samples/populations required for the study.

  ○ Whether there is sufficient information provided regarding the subject-to-group assignments process (if applicable).

  ○ How well the types of specimens or data to be collected and evaluated and the storage of specimens are described.

  ○ How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.

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

- **Budget**

  ○ Whether the **direct** maximum costs are equal to or less than the allowable direct maximum 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.

- **Environment**

  ○ If applicable, to what degree the intellectual and material property plan is appropriate.

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 FY19 TBDRP, as evidenced by the following:

  ○ Adherence to the intent of the award mechanism

  ○ Programmatic relevance in relation to the FY19 TBDRP Focus Areas

  ○ Relative impact, including impact on public health burden and burden on military Service members

  ○ Program portfolio balance

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, USAMRMC, 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. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the TBDRP 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 <u>Section I, Overview of the Funding Opportunity</u>.

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 FY19 funds are anticipated to be made no later than September 30, 2020. 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.

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.

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

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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

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

II.F.3. Reporting

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

Quarterly technical progress reports with quad charts, annual progress reports, and a final progress report will be required.

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 20190218c. The Program Announcement numeric version code will match the General Application Instructions version code 20190218.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY19 TBDRP 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 FY19 TBDRP Programmatic Panel members can be found at https://cdmrp.army.mil/tbdrp/panels/panels19.*

- 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 FY19, 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.

- Applications submitted by an intramural DoD organization 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.

- A clinical trial is proposed.

- The PI or Mentor does not meet the eligibility criteria.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Relevance Statement: Upload as Attachment 7 with file name "Relevance.pdf"	
	Career Development Plan: Upload as Attachment 8 with file name "CareerDev.pdf"	
	Eligibility Statement: Upload as Attachment 9 with file name "Eligibility.pdf"	
	Letter from Mentor: Upload as Attachment 10 with file name "MentorLetter.pdf"	
	Human Subjects/Sample Acquisition and Safety Procedures: Upload as Attachment 11 with file name "HumSubProc.pdf"	
	Representations (Extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable	
	DoD Military Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CDA	Career Development Award
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBDRP	Tick-Borne Disease Research Program
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs