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

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524TBDRPIDA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), June 26, 2024
- **Invitation to Submit an Application:** August 7, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 3, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 8, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** February 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Tick-Borne Disease Research Program (TBDRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the TBDRP in 2016 to support innovative and impactful research that addresses fundamental issues and gaps in knowledge of tick-borne diseases. Appropriations for the TBDRP from FY16 through FY23 totaled $48.0 million (M). The FY24 appropriation is $7.0M.

The TBDRP's vision is to eliminate the health burden of tick-borne diseases. The TBDRP's mission is to fund innovative research to understand and provide solutions to prevent, detect, and resolve Lyme disease and other tick-borne diseases and conditions for the benefit of Service Members, Veterans, their Families and the American public.

II.A.1. FY24 TBDRP Idea Development Award Focus Areas

To meet the intent of the funding opportunity, applications submitted to the FY24 TBDRP should be focused on Lyme disease and/or other tick-borne diseases/conditions with emphasis on reducing the public health burden of these illnesses. ***Particularly encouraged are applications focused on persistent Lyme disease and other tick-borne diseases and conditions endemic to the United States (https://www.cdc.gov/ticks/data-summary/index.html).***

Idea Development Award applications must respond to at least one of the following specific FY24 TBDRP Idea Development Award Focus Areas:

- **Pathogenesis**
    - Studies to assess the interaction among tick-borne pathogens in mammals, and consequences on pathogen synergy and competition, immune responses, or disease severity, with an emphasis on Lyme disease and its associated co-infections
    - Studies of immune evasion, host tolerance, or pathogen-host immunosuppression associated with Lyme disease and/or other tick-borne infections
    - Studies of persistent clinical manifestations associated with Lyme disease, with studies providing insight into neurologic symptoms particularly encouraged
    - Studies, including epidemiologic or animal studies, to evaluate the role of tick-borne diseases on maternal health and pregnancy outcomes, improve understanding of congenital tick-borne infections, and/or assess the impact of maternal-to-fetal transmission of tick-borne infections

- **Treatment**
    - Proof-of-concept studies for the development of novel therapeutics, or studies to support the repurposing of available or approved compounds for improved treatment of tick-borne diseases
    - Target identification and/or validation and early refinement of therapeutic candidates, including but not limited to high throughput screening, lead optimization, and structure/activity relationship studies
- **Diagnosis**
    - Development and optimization of innovative approaches that provide diagnostic advantages for single or multiple tick-borne pathogens, with priority given to direct detection or multiplex tests
    - Development and optimization of more accurate or novel approaches capable of distinguishing active Lyme disease infection from previous exposure and/or resolution of infection
    - Development and optimization of approaches for the detection/diagnosis of maternal-to-fetal transmission of Lyme disease and/or other tick-borne infections to guide treatment of resulting infection, including the development of relevant animal models

Applications proposing the following will be considered non-responsive to this mechanism: human vaccine work, field work of tick or reservoir hosts, studies related to mammalian meat allergy (allergic response to galactose-alpha-1,3-galactose [alpha-gal]), or studies related to Lyme arthritis.

Applications proposing studies focused on evaluating/validating demonstrated therapeutic candidates or diagnostic approaches for tick-borne diseases/conditions are not within the scope of this funding opportunity; applicants should consider submitting under funding opportunity number ***HT942524TBDRPTDRA.***

II.A.2. Award History

The TBDRP Idea Development Award mechanism was first offered in FY20. Since then, 206 Idea Development Award applications have been received, and 18 have been recommended for funding.

II.B. Award Information

The FY24 TBDRP Idea Development Award is intended to support conceptually innovative research that could lead to impactful discoveries or significant advancements that will accelerate progress toward reducing the burden of Lyme disease and/or other tick-borne diseases and conditions and improve patient care, and/or the quality of life for military Service Members, Veterans, and their Families, as well as the American public.

Research supported by an **Idea Development Award** should be conceptually innovative, introduce a new concept or question, challenge existing paradigms, approach issues from a new perspective, or exhibit other uniquely creative qualities and should not merely be a next logical step or an incremental advance on published data or ongoing research. ***Inclusion of preliminary data relevant to the proposed studies is neither required nor prohibited for the Idea Development Award; however, in its absence, strong rationale for achieving interpretable results must be provided.***

The following examples are ways in which **Idea Development Awards** may be innovative and are intended to help PIs frame the innovative features of their applications. ***This list is not all-inclusive***.

- *Novel research method or technology:* Development or use of novel research methods or new technologies to address a fundamental research question capable of changing patient care in Lyme disease and/or other tick-borne diseases.

- *Existing method or technology:* Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended, including applying knowledge/methods from other fields.

- *Communication and dissemination of information:* Development or use of novel platforms or networks for the communication and dissemination of validated research or clinical information with the purpose of increasing awareness and educating patients or clinicians/providers.

A **Career Development Option** is available to eligible early-career investigators who propose to conduct impactful research under the mentorship of an experienced tick-borne disease researcher. The Idea Development Award – Career Development Option has a lower direct cost limit than the Idea Development Award, and applications submitted under the Idea Development Award – Career Development Option **will be reviewed via separate, career development-specific evaluation criteria by a separate, dedicated peer review panel.** ***Inclusion of preliminary data relevant to the proposed studies is neither required nor prohibited; however, in its absence, strong rationale for achieving interpretable results must be provided.***

The following are key aspects of the **Idea Development Award – Career Development Option**:

- **Principal Investigator (PI):** The PI must be an early-career research scientist, physician scientist, or other qualified clinical scientist within 10 years of completing their 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 their potential for contributing to the field of tick-borne disease 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 50% level of time and effort during the period of performance to conduct tick-borne disease research, although more protected time is highly desirable.

- **Mentorship:** The mentor(s) must be experienced tick-borne disease researcher(s), as demonstrated by a recent (last 5 years) history of funding and publications in tick-borne disease research and should ideally have experience mentoring other independent scientists. Collectively, the PI/mentorship team should have demonstrated experience in the field (pathogen/disease and associated methods/technologies) of the proposed studies. The mentor(s) must hold a position at or above the level of Associate Professor (or equivalent). In addition, the mentor(s) must demonstrate a commitment to developing the PI's career in tick-borne disease research and should remain engaged for the entire duration of the project. The mentor(s) and PI may be at different organizations; however, a clear indication of how the mentor(s) will communicate with and facilitate the PI's career development should be provided in the Career Development Plan, as described below. Additional mentors who provide complementary expertise and may be at different institutions than the primary mentor are welcomed and encouraged. These additional mentors are not required to meet the same obligations as the primary mentor with respect to funding, publications, and previous experience in tick-borne disease research.

- **Career Development Plan:** A Career Development Plan is required and should be prepared by the PI with appropriate guidance from the mentor(s). The plan should outline how the PI will gain experience in tick-borne disease research and engage with the tick-borne disease scientific and advocacy communities (as applicable). A clearly articulated strategy for acquiring the necessary skills, competence, and expertise to establish a career at the forefront of tick-borne disease research should be included, as well as a plan for how the mentor(s) will engage with the PI to contribute to the PI's career development as a tick-borne disease researcher and to the success of the proposed research for the duration of the project.

The following applies to both the Idea Development Award and the Idea Development Award-Career Development Option:

- ***Preliminary Data: Inclusion of preliminary data relevant to the proposed studies is neither required nor prohibited, however in its absence, strong rationale for achieving interpretable results must be provided.***

- Applications must describe the evidence-based burden of disease on public health and how the proposed research may alleviate that burden in the short- and long-term. This award mechanism promotes basic through translational research, including preclinical and clinical research, as well as correlative studies associated with an existing clinical trial to establish proof-of-principle for further development in future studies.

- ***Animal studies that evaluate novel treatment regimens for acute and persistent Lyme disease and/or co-infections, when accompanied by proper scientific justification and rationale, appropriate protocols and controls, are welcomed. Research involving human subjects and human biospecimens is permitted; however, clinical trials are not allowed under this program announcement.***

- ***Leveraging existing resources, maximizing statistical power, and using validated biospecimens and data from Lyme and other tick-borne disease biorepositories and databases are encouraged, but not required.*** 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-characterized, to the extent practicable based on the indication, cohorts of 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 novel genomic and/or proteomic analysis, bioinformatics, and/or mathematical models to such data are also encouraged. The criteria defining the inclusion/exclusion of curated biospecimens or data in biorepositories or databases must be described to demonstrate the validity of their use in the proposed studies.

- **Department of Defense (DOD) and U.S. Department of Veterans Affairs (VA) Collaboration and Alignment Encouraged:** Relevance to the healthcare needs of the Armed Forces and Veterans, as well as their Family members, caregivers, or clinicians, is a key feature of this award. Therefore, applicants are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with the DOD and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 TBDRP Idea Development Award should not exceed **$525,000**. The anticipated direct costs budgeted for the entire period of performance for an FY24 TBDRP Idea Development Award – Career Development Option should not exceed **$350,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $3.64M to fund approximately three Idea Development Award applications and two Idea Development Award – Career Development Option applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirement.

II.C.1.b. Principal Investigator

For the Idea Development Award:

Independent investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the PI on the application.

For the Idea Development Award – Career Development Option:

- **PI**
    - The PI must be an early-career research scientist, physician scientist, or other qualified clinical scientist, within 10 years of completion of their 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 must be demonstrated, including confirmation of laboratory space and a minimum of 50% level of time and effort during the period of performance for the PI to conduct tick-borne disease research.
- **Mentor**
    - The mentor(s) must hold a position at or above the level of Associate Professor (or equivalent).
    - The mentor(s) must be experienced researcher(s) as demonstrated by a recent (last 5 years) history of funding and publications in tick-borne disease research and should ideally have experience mentoring other independent scientists. Collectively, the PI/mentorship team should have demonstrated experience in the field (pathogen/disease and associated methods/technologies) of the proposed studies. The mentor(s) must demonstrate a commitment to developing the PI's career in tick-borne disease research.

The PI and the mentor(s) 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.

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

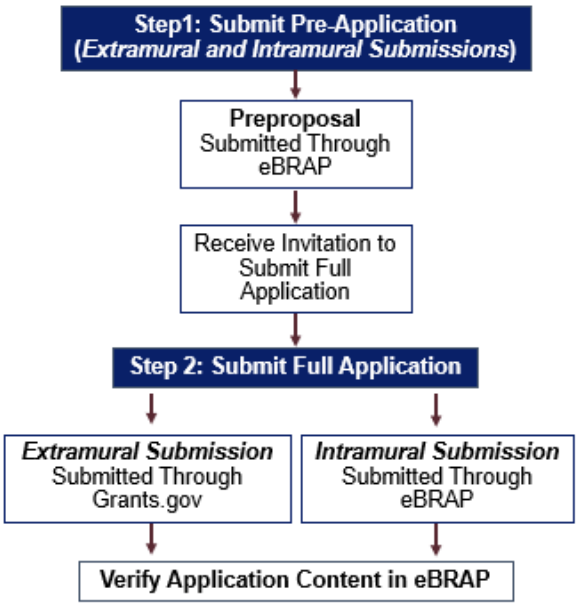
II.D.1. Location of Application Package

Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524TBDRPIDA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524TBDRPIDA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

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

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 TBDRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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

For Career Development Option submissions, no change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
NO human subjects, human biological samples (prospective or retrospective, including de-identified) or human data sets	Idea Development Award
Any human subjects, human biological samples (prospective or retrospective, including de-identified) or human data sets	Idea Development Award, involving Human Subjects/Sample Acquisition
NO human subjects, human biological samples (prospective or retrospective, including de-identified), or human data sets, with submission to the Career Development Option (for additional information refer to Section II.B, Award Information)	Idea Development Award – Career Development Option
Any human subjects, human biological samples (prospective or retrospective, including de-identified), or human data sets, with submission to the Career Development Option (for additional information refer to Section II.B, Award Information)	Idea Development Award – Career Development Option, involving Human Subjects/Sample Acquisition

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

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

  The Preproposal Narrative should include the following:

  - **Research:** State a clear hypothesis for the project that is supported through scientific rationale, referenced literature, **and/or** preliminary data (***if applicable***). Inclusion of preliminary data relevant to the proposed studies is neither required nor prohibited, however in its absence, strong rationale for achieving interpretable results must be

provided. Describe the study type (e.g., concept development, animal validation, human validation), project specific aims, and scientific approach.

- **Relevance:** Summarize the relevance of the proposed project to the FY24 TBDRP Idea Development Award Focus Areas. ***Note: Pre-applications proposing the following will be considered non-responsive to this mechanism: human vaccine work, field work of tick or reservoir hosts, studies related to mammalian meat allergy (allergic response to galactose-alpha-1,3-galactose [alpha-gal]), or studies related to Lyme arthritis.***

- **Impact:** Describe how this research will reduce the incidence and/or burden of Lyme disease and/or other tick-borne diseases or conditions. Describe the immediate and long-range outcomes of the proposed study and how they will advance knowledge and/or technology toward improved patient care and/or quality of life for military Service Members, their Families, and members of the American public affected by Lyme disease and/or other tick-borne diseases or conditions. If applicable, describe how the proposed work will be relevant to the future development of new treatments or diagnostic tests.

- **Innovation (*not required for the Idea Development Award – Career Development Option*):** Describe how the proposed study is innovative and represents more than an incremental advance upon published data. For examples of ways that the proposed work may be innovative, refer to Section II.B, Award Information.

- **Mentor (*required only for the Idea Development Award – Career Development Option*):** Provide the name and institution of the mentor(s) and describe how planned interactions with the PI demonstrates a commitment to the PI's career development as a tick-borne disease researcher and to the success of the proposed research for the duration of the project.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

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

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (six-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the TBDRP, pre-applications will be screened based on the following criteria:

- **Research:** How well a clear hypothesis for the project is stated with support from scientific rationale and referenced literature and how well the study type, specific aims, and scientific approach are described.

- **Relevance:** To what degree the proposed project is relevant to the FY24 TBDRP Idea Development Award Focus Area(s) being addressed. ***Pre-applications proposing the following will be considered non-responsive to this mechanism: human vaccine work, field work of tick or reservoir hosts, studies related to mammalian meat allergy (allergic response to galactose-alpha-1,3-galactose [alpha-gal]), or studies related to Lyme arthritis.***

- **Impact:** The extent to which the anticipated research outcomes will reduce the incidence and/or burden of Lyme disease and/or other tick-borne diseases or conditions. The extent to which the research outcomes will advance knowledge and/or technology toward improved patient care and/or quality of life for individuals with Lyme disease and/or other tick-borne diseases or conditions. The extent to which the research outcomes are relevant to the future development of new treatments or diagnostic tests, as applicable.

- **Innovation (*applicable only to the Idea Development Award*):** To what degree the proposed research is innovative and represents more than an incremental advance upon published data.

- **Mentor (*applicable only to the Idea Development Award – Career Development Option*):** To what degree planned interactions with the PI demonstrate a commitment to the PI's career development as a tick-borne disease researcher and to the success of the proposed research for the duration of the project.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (12-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  The Idea Development Award and the Idea Development Award – Career Development Option have different Project Narrative requirements. Refer to the correct outline below for applications submitted to each corresponding award mechanism option.

The Project Narrative for applications submitted under the Idea Development Award should include the following:

- **Background/Rationale:** Describe the problem, issue, or gap in an area of patient care that is related to at least one of the FY24 TBDRP Idea Development Award Focus Areas and will be addressed by the proposed research. Describe previous experience most pertinent to the proposed research. Include relevant literature citations and preliminary data (if applicable) to support the study's feasibility. Any unpublished preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team. **In the absence of preliminary data, strong rationale for achieving interpretable results must be provided.**

- **Hypotheses/Objectives:** State the hypotheses/study questions and overall objective(s) to be reached.

- **Specific Aims:** Concisely explain the project's specific aims in support of the hypothesis/objectives. If this application is part of a larger study, present only tasks that this award would fund. ***Avoid interdependency of Specific Aims***. Proposed studies should not be dependent upon the successful outcomes, products, or samples from other ongoing research efforts.

- **Research Strategy:** Describe the experimental design, methods, estimated sample size(s), 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.

  - Describe what aspects of the study the PI and other key personnel will be responsible for and what level of effort they will put forth to ensure successful conduct of the proposed work.

  - Address potential problems and provide approaches to mitigate these concerns, including interdependency of aims or dependency on successful outcomes, products, or samples from other ongoing research efforts.

  - Details of research involving human subjects or human biospecimens will be required in Attachment 7, as applicable. ***This award cannot be used to conduct clinical trials.***

  - Details of research involving animals will be required in Attachment 8, as applicable.

  - If cell lines are to be used, describe how the choice of proposed cell line(s) is justified and relevant to human biology and natural tick-borne disease transmission. Include information about authentication of proposed cell lines. Describe the statistical rigor of in vitro cellular studies.

- **Innovation:** Explain how the proposed work is innovative and not merely a next logical step or an incremental advance on any published data or any ongoing research. Describe how the research introduces a new concept or question, challenges existing paradigms, approaches issues from a new perspective, or exhibits other uniquely creative qualities. For examples of ways that the proposed work may be innovative, refer to Section II.B, Award Information.

- **Collaboration (if applicable):** Describe how the specific contributions of collaborators will complement the PI's ability to perform the proposed work, enhance the project's innovation or impact in the tick-borne diseases research field, and/or promote collaboration among fields or with commercial partners.

The Project Narrative for applications submitted under the Idea Development Award – Career Development Option should include the following:

- **PI:** Describe the PI's potential for a career at the forefront of tick-borne disease research, including qualifications and achievements that make the PI an ideal candidate for this award. Discuss how the PI's record of accomplishments (within or outside the field of tick-borne diseases) and letters of support demonstrate their potential for advancement as a productive, independent investigator in tick-borne disease research. Describe the PI's career goals as a tick-borne disease researcher and/or clinician and how the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of tick-borne disease research. Discuss how the proposed research project itself is appropriate for advancing the PI's independent career at the forefront of tick-borne disease research. Describe the appropriateness of the level of effort of the PI for successful conduct of the proposed research.

- **Mentor:** Describe the qualifications of the mentor(s), including recent (last 5 years) history of funding and publications in tick-borne disease research, as well as a description of their mentoring history (if applicable). Collectively, the PI/mentorship team should have demonstrated experience in the field (pathogen/disease and associated methods/technologies) of the proposed studies. Describe the track record of the mentor(s) in mentoring early-career investigators (if applicable) to indicate the potential for successful mentorship and development of the PI's independent career in tick-borne disease research. Describe how the mentor(s) demonstrate a commitment to the PI's career development as a tick-borne disease researcher and to the success of the proposed research for the duration of the project through proposed direction and oversight. Clearly outline plans for regular, sustained interactions and communications between the PI and mentor(s).

- **Research**

  - **Background/Rationale:** Describe the problem, issue, or gap in an area of patient care that is related to at least one of the FY24 TBDRP Idea Development Award Focus Areas and that will be addressed by the proposed research. Describe the previous experience of the PI and mentor(s) that are most pertinent to the

proposed research. Include relevant literature citations and/or preliminary data (if applicable) to support the study's feasibility.

- **Preliminary Data:** Inclusion of preliminary data relevant to the proposed studies is neither required nor prohibited, however in its absence, strong rationale for achieving interpretable results must be provided. If included, preliminary data may be from the laboratory of the PI, mentor(s), or member(s) of the collaborating team, or from the appropriate literature.

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

- **Specific Aims:** Concisely explain the project's specific aims in support of the hypothesis/objectives. If this application is part of a larger study, present only tasks that this award would fund. ***Avoid interdependency of Specific Aims***. Proposed studies should not be dependent upon the successful outcomes, products, or samples from other ongoing research efforts.

- **Strategy:** Describe the experimental design, methods, estimated sample size(s), 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. Describe what aspects of the study the PI and other key personnel will be responsible for and what level of effort they will put forth to ensure successful conduct of the proposed work.

- Address potential problems and provide approaches to mitigate these concerns, including interdependency of aims or dependency on successful outcomes, products, or samples from other ongoing research efforts.

- Details of research involving human subjects or human biospecimens will be required in Attachment 7, as applicable. ***This award cannot be used to conduct clinical trials.***

- Details of research involving animals will be required in Attachment 8, as applicable.

- If cell lines are to be used, describe how the choice of proposed cell line(s) is justified and relevant to human biology and natural tick-borne disease transmission. Include information about authentication of proposed cell lines. Describe the statistical rigor of in vitro cellular studies.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

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

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

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

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)*:** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."

    - **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

    - **Commercialization Strategy *(if applicable)*:** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and

management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to the CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's 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 signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Inclusion Enrollment Plan *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race

(typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at (https://ebrap.org/eBRAP/public/Program.htm).

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

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the ideas and logical reasoning behind the proposed work as it relates to the FY24 TBDRP Idea Development Award Focus Areas.

  - **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 (***required for all applications***). Describe how the proposed study is innovative (***not required for applications submitted under the Idea Development Award – Career Development Option)***.

  - **Impact:** Describe the impact of the proposed study on Lyme disease and/or other tick-borne diseases/conditions research, and on patient care and quality of life for military Service Members and the American public.

  - **Career Development (*required only for applications submitted under the Idea Development Award – Career Development Option*):** Describe the PI's career goals in tick-borne diseases research and how the proposed research and Career Development Plan support those goals.

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

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

- State the FY24 TBDRP Idea Development Award Focus Area(s) the project addresses.

- Describe the ultimate applicability of the research.

  - What is the project's potential impact on reducing the public health burden of tick-borne diseases/conditions, 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?

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

  - If the research is too basic for immediate clinical applicability, describe the interim outcomes.

  - What are the likely contributions of the study to advancing the field of Lyme disease and/or other tick-borne diseases research?

- **Career Development (*required only for applications submitted under the Idea Development Award – Career Development Option*):** Describe the PI's career goals in tick-borne diseases research and how the proposed research and Career Development Plan support those goals.

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested Statement of Work (SOW) format and recommended strategies for assembling the SOW.

  For the Idea Development Award mechanism, refer to the "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Explain in detail how the proposed project will address a critical problem in Lyme disease and/or other tick-borne diseases/conditions and/or will impact the FY24 TBDRP Idea Development Award Focus Area(s) being addressed as follows:

  - **Public Health Burden:** Describe the burden of illness for the disease(s) or condition(s) to be studied, including current evidence-based public health information on mortality, morbidity, and economic impact. Describe in detail how the proposed research will ultimately reduce the burden of Lyme disease and/or other tick-borne illnesses and their effect on public health. Describe how the research is focused on tick-borne diseases and conditions endemic to the United States and/or involves persistent Lyme disease.

- **Military Relevance:** Describe how the proposed research is relevant to and will specifically impact the healthcare needs and welfare of military Service Members, Veterans, and their Families in a way that is consistent with the program's goals.

  The following resources include data on tick-borne diseases in the military and can be used in developing the Impact Statement:

  - Medical Surveillance Monthly Report Feb 2021 (Vol 28, No 2) (https://www.health.mil/MSMRArchives)
  - Medical Surveillance Monthly Report May 2022 (Vol 29, No 5) (https://www.health.mil/MSMRArchives)
  - Medical Surveillance Monthly Report Jan 2024 (Vol 31, No 1) (https://www.health.mil/MSMRArchives)

  PIs are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with the DOD and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 2.

- **Short-Term Impact:** Detail the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) that can be directly attributed to the proposed research.

- **Long-Term Impact:** Explain the anticipated long-term advancements over current knowledge, technology, and/or practice, ultimately contributing to the field of Lyme disease and/or other tick-borne diseases/conditions research, patient care, and morbidity and/or mortality. For studies focused on pathogenesis topics, an acceptable long-term gain may be filling a significant gap in the foundational knowledge of the disease and/or pathogen or having demonstrated downstream applicability to new treatments or diagnostic tests. Describe how such mechanistic research could lead to possible strategies for intervention and/or prevention, or novel diagnostic approaches, if applicable.

- **Attachment 7: Human Subjects/Sample Acquisition and Safety Procedures (*applicable and required for all applications submitted under the Idea Development Award, involving Human Subjects/Sample Acquisition or the Idea Development Award – Career Development Option, involving Human Subjects/Sample Acquisition*) (no page limit): Upload as "HumSubProc.pdf".** If the proposed study involves human subjects, human biological samples (prospective or retrospective, including de-identified), or human data sets, the applicant is required to submit the Human Subjects/Sample Acquisition and Safety Procedures attachment to include the components listed below. ***Proposed studies should not rely on samples, reagents, or tools that are contingent upon completion of other ongoing efforts outside the scope of this proposal.***

- Describe the study population and explain how well the sample population is designed to achieve the study objectives, including relevance of the population and endpoints/outcome measures to be used.

- Describe the nature, approximate number, and pertinent demographic characteristics of the study population, and provide a table of anticipated enrollment counts at each site, as applicable.

- Describe the methods for sample acquisition and/or human subjects recruitment in detail.

- Describe the informed consent process and include relevant draft process documents and consent forms, if applicable. It is recommended that informed consent allows for the use of samples for future studies and recontact of participants for potential involvement in additional research.

- List the inclusion and exclusion criteria and provide detailed justification for limiting inclusion of any group by age, race, ethnicity, or sex/gender.

- Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

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

- Provide sufficient evidence to support availability of and access to populations/samples required for the study and document the experience of the PI and/or key collaborators in recruiting human subjects/acquiring human samples or data for similar projects.

- Address any potential barriers to accrual, including access to the proposed study samples/populations, and present contingency plans for addressing unanticipated delays, including other ongoing studies competing for the same samples/populations, slow or low enrollment, or poor retention, as applicable.

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

- Describe how the study will take into consideration patient-centered outcomes, patient values and preferences among treatment alternatives, and shared decision-making in encounters between physicians and patients.

- If retrospectively collected human biological samples or human data sets from biorepositories or databases will be used, describe how those curated samples or data

are representative of well-characterized cohorts of patients by providing their defining inclusion/exclusion criteria.

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

- Provide a statistical plan and sample size estimate for each study arm, including rationale for number of samples and/or power analysis calculations to demonstrate that the sample size is appropriate to meet the objectives of the study.

- Describe how data will be handled, including the rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and managed, and identification of the primary endpoint(s).

- 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).

- **Attachment 8: Animal Research Plan (*applicable and required for applications proposing animal studies*) (three-page limit): Upload as "AnimalResPlan.pdf".** If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. ***Proposed studies should not rely on samples, reagents, or tools that are contingent upon completion of other ongoing efforts outside the scope of this proposal.*** Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting In Vivo Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology and natural tick-borne disease transmission.

  - Summarize the procedures to be conducted. Describe how the study will be controlled.

  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of the results. If randomization and/or blinding will not be utilized, provide justification.

- Provide a sample size estimate for each study arm and the method by which it was derived, including rationale for number of samples and/or power analysis calculations.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 9: Career Development Plan (*required only for applications submitted under the Idea Development Award – Career Development Option or the Idea Development Award – Career Development Option, involving Human Subjects/Sample Acquisition*) (three-page limit): Upload as "CareerDev.pdf".** The Career Development Plan attachment should be prepared by the PI with appropriate guidance from the mentor(s).

  - Provide a signed cover letter from the mentor(s) indicating recommendation, support, and planned interactions with the PI for the proposed work. The mentor(s) should plan to be involved for the entire period of performance and therefore the cover letter should address the ability of the mentor(s) to dedicate time to engage with the PI throughout the award. The cover letter from the mentor(s) should specifically detail plans for individualized interaction with the PI and the modality and frequency of the interactions to facilitate the PI's career development. Include information on the record of the mentor(s) in preparing early-career investigators for careers in tick-borne disease research.

  - 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 disease research.

  - Indicate specifically how the individualized Career Development Plan will provide the PI with an opportunity to acquire the necessary skills, competence, and expertise to establish/advance their independent career in tick-borne disease research, as well as how the mentor(s) will contribute to the PI's career development as a tick-borne disease researcher and to the success of the proposed research for the duration of the project. Outline how the PI will gain experience in tick-borne disease research and engage with the tick-borne disease scientific and advocacy communities (as applicable), for example via workshops, seminars, etc.

  - Describe how the Career Development Plan is supported by other tick-borne disease researchers at the PI's institution and/or potential collaborations with tick-borne disease investigators at other institutions (if applicable).

- **Attachment 10: Letter of Eligibility (*required only for applications submitted under the Idea Development Award – Career Development Option or the Idea Development Award – Career Development Option, involving Human Subjects/Sample Acquisition*) (one-page limit): Upload as "Eligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements

have been met. The letter should verify that the PI is an early-career research or physician scientist within 10 years of completion of their terminal degree (excluding time spent in residency or on family medical leave; refer to Section II.C, Eligibility Information). Include the institutional commitment of laboratory space and a minimum of 50% level of time and effort during the period of performance for the PI to conduct tick-borne disease research.

- **Attachment 11: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (six-page limit):** Upload as "Biosketch_LastName.pdf".

- **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".

  - ***For the Idea Development Award – Career Development Option:*** Include biographical sketch of mentor(s).

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

- ***For the Idea Development Award – Career Development Option:*** Include previous/current/pending support of mentor(s).

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

II.D.5. Funding Restrictions

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

Idea Development Award: The application's direct costs budgeted for the entire period of performance should not exceed **$525,000.** If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

Idea Development Award – Career Development Option: The anticipated direct costs budgeted for the entire period of performance should not exceed **$350,000.** If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 TBDRP Idea Development Award.

Must not be requested for:

- Clinical trial costs

- Mentor registration and/or travel costs
- Mentor salary

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Impact**
    - To what extent the proposed project will address a critical problem in Lyme disease and/or other tick-borne diseases/conditions and/or will impact the FY24 TBDRP Idea Development Award Focus Areas.
    - To what extent the proposed research will ultimately reduce the burden of Lyme disease and/or other tick-borne illnesses and their effect on public health.
    - How the research is focused on tick-borne diseases and conditions endemic to the United States, and/or involves persistent Lyme disease.
    - To what extent the proposed research is relevant to and will specifically impact the healthcare needs and welfare of military Service Members, Veterans, and their Families in a way that is consistent with the program's goals.
    - How the anticipated short-term outcome(s)/products(s) (intellectual and/or tangible) can be directly attributed to the proposed research.
    - How the anticipated long-term advancement over current knowledge, technology, and/or practice that would ultimately contribute to the field of Lyme disease and/or other tick-borne diseases/conditions research, patient care, and morbidity and/or mortality can be directly attributed to the proposed research. If applicable, to what extent mechanistic research could lead to possible strategies for intervention and/or prevention, or novel diagnostic approaches.
- **Research Strategy and Feasibility**
    - How well the background/rationale describes a problem, question, or knowledge gap that will be addressed by the proposed research.

- How well the application presents the scientific rationale behind the proposed work and includes relevant literature citations **and/or** preliminary data to support the study's feasibility. ***Preliminary data are neither required nor prohibited; however, in its absence, strong rationale for achieving interpretable results must be provided.***

- How well the application states appropriate hypotheses/study questions and overall objective(s) to be reached, along with specific aims in support of the hypothesis/objectives.

- How well the application describes the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation of feasibility.

- How well the application acknowledges potential problems and provides approaches to mitigate those concerns, including interdependency of aims or dependency on successful outcomes, products, or samples from other ongoing research efforts.

- For research involving cell line(s) and/or animals:

  - How well the choice of proposed cell line(s) and/or animal model(s) is justified and relevant to human biology and natural tick-borne disease transmission.

  - To what extent the endpoints/outcome measures are appropriate to achieve study objectives.

  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation including rationale for number of samples and/or power analysis calculations, blinding, randomization, and data handling.

- **Human Subjects/Sample Acquisition and Safety Procedures (*for applications submitted under an option involving Human Subjects/Sample Acquisition*)**

  - The degree to which the study population, the methods for sample acquisition and/or human subjects recruitment, the informed consent process, and the screening procedures 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 and documentation of the experience of the PI and/or key collaborators in recruiting human subjects/acquiring human samples or data for similar projects.

  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

  - How well the application addresses any potential barriers to accrual, including access to the proposed study samples/populations, and presents adequate contingency plans for addressing potential delays. How well the application identifies potential ethical issues

raised by the proposed study and provides a detailed plan for how those issues will be addressed.

- How well the study takes into consideration patient-centered outcomes, patient values and preferences among treatment alternatives, and shared decision-making in encounters between physicians and patients.

- If retrospectively collected human biological samples or human data sets from biorepositories or databases will be used, whether the curated samples or data are representative of well-characterized cohorts of patients as demonstrated by their defining inclusion/exclusion criteria.

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

- Whether the application includes an appropriate statistical plan and sample size estimate for each study arm, including rationale for number of samples and/or power analysis calculations to demonstrate that the sample size is appropriate to meet the objectives of the study given the constraints of the award mechanism.

- Whether the application describes how data will be handled, including the rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and managed, and identification of primary endpoints.

- How well the types of specimens or data to be collected and evaluated, and specimen storage and maintenance, are described.

- **Innovation (*applicable only to the Idea Development Award*)**

  - To what degree the proposed work is innovative and not merely a next logical step or an incremental advance on any published data or any ongoing research.

  - Without considering preliminary data, to what extent the research introduces a new concept or question, challenges existing paradigms, approaches issues from a new perspective, or exhibits other uniquely creative qualities.

- **Personnel (*applicable only to the Idea Development Award*)**

  - Based on PI and Key Personnel Biographical Sketches, to what degree the research team's background is appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise (as applicable).

  - To what degree the levels of effort of the PI and other key personnel are appropriate to ensure successful conduct of the proposed work.

  - How well the specific contributions of collaborators will complement the PI's ability to perform the proposed work, enhance the project's innovation or impact in the tick-borne

disease research field, and/or promote collaboration among fields or with commercial partners (if applicable).

- **PI (*applicable only to the Idea Development Award – Career Development Option*)**
    - Whether the PI meets the eligibility requirements.
    - To what extent the PI's record of accomplishments (within or outside the field of tick-borne diseases) and letters of support demonstrate their potential for advancement as a productive, independent investigator in tick-borne disease research.
    - To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of tick-borne disease research.
- **Career Development Plan (*applicable only to the Idea Development Award – Career Development Option*)**
    - How well the PI has outlined a detailed, individualized Career Development Plan that will provide the PI with the opportunity to acquire the necessary skills, competence, and expertise to effectively establish/advance their independent career in tick-borne disease research.
    - To what degree the proposed Career Development Plan outlines how the PI will gain experience in tick-borne disease research and engage with the tick-borne disease scientific and advocacy communities (as applicable), for example via workshops, seminars, etc.
    - To what degree the mentor(s) demonstrates a commitment to the PI's career development as a tick-borne disease researcher and to the success of the proposed research for the duration of the project through proposed direction and oversight and how well plans for regular, sustained interactions and communication between the PI and mentor(s) are clearly outlined.
    - How well the application describes the qualifications of the mentor(s), including recent (last 5 years) history of funding and publications in tick-borne disease research, as well as a description of their mentoring history (if applicable), and whether, collectively, the PI/mentorship team has demonstrated experience in the field (pathogen/disease and associated methods/technologies) of the proposed studies.
    - To what degree the track record of the mentor(s) in mentoring early-career investigators (if applicable) indicates the potential for successful mentorship and development of the PI's independent career in tick-borne disease research.
    - Appropriateness of the levels of effort of the PI, mentor(s), and other key personnel for successful conduct of the proposed research.

- To what extent the Career Development Plan is supported by other tick-borne disease researchers at the PI's institution and/or potential collaboration with tick-borne disease investigators at other institutions (if applicable).

- Whether there is a clear institutional commitment to allow protection of a minimum of 50% level of time and effort during the period of performance for the PI to conduct tick-borne disease research.

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

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

- **Environment**

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

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

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

- **Budget**

  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.

  - Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers

- Relevance to the priorities of the DHP and FY24 TBDRP, as evidenced by the following:

  - Adherence to the intent of the funding opportunity

- Programmatic relevance in relation to the FY24 TBDRP Idea Development Award Focus Areas
- Relative impact, including impact of public health burden and burden on military Service Members and their Families
- Program portfolio composition

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***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.health.mil/about/2tierRevProcess.

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a

recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the TBDRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

For the Idea Development Award: Changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

For the Idea Development Award – Career Development Option: 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. Changes in organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism and option is met.

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

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

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

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports and quad charts as well as a final technical progress report and quad chart will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

PHS Inclusion Enrollment Reporting Requirement ***(only required if clinical research is conducted)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10.0M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the full application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 TBDRP Programmatic Panel members can be found at https://cdmrp.health.mil/tbdrp/panels/panels24***.
- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and

the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- For applications involving human subjects, human biological samples (prospective or retrospective, including de-identified), or human data sets, the Human Subject/Sample Acquisition and Safety Procedures (Attachment 7) is missing.
- For applications involving animals, the Animal Research Plan (Attachment 8) is missing.
- The application fails to address at least one of the FY24 TBDRP Idea Development Award Focus Areas.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Submission of the same research project to both the Idea Development Award and the Idea Development Award – Career Development Option.
- The invited application proposes a different research project than that described in the pre-application.
- A clinical trial is proposed.
- The PI 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. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Human Subjects/Sample Acquisition Safety Procedures *(if applicable)* – Attachment 7, upload as "HumSubProc.pdf"	☐
Animal Research Plan *(if applicable)* – Attachment 8, upload as "AnimalResPlan.pdf"	☐
Career Development Plan *(if applicable)* – Attachment 9, upload as "CareerDev.pdf"	☐
Letter of Eligibility *(if applicable)* – Attachment 10, upload as "Eligibility.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐
Additional Application Components	☐
Confidential Letters of Recommendation	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
TBDRP	Tick-Borne Disease Research Program
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

APPENDIX 2: DOD AND VA WEBSITES

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

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

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

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://cccrp.health.mil/Pages/default.aspx

Congressionally Directed Medical Research Programs
https://cdmrp.health.mil/

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

Defense Health Agency
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/

Defense Suicide Prevention Office
https://www.dspo.mil/

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

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

Military Health System Research Symposium
https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program
https://midrp.health.mil/

Military Operational Medicine Research Program
https://momrp.health.mil/

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

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

Naval Medical Research Command
https://www.med.navy.mil/Naval-Medical-Research-Command/

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

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

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

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

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

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

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

U.S. Army Medical Materiel Development Activity
https://usammda.health.mil/

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

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

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

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

U.S. Army Sharp, Ready and Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

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

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

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

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