Program Announcement for the Defense Health Agency

Tuberous Sclerosis Complex Research Program

Clinical Translational Research Award

Funding Opportunity Number: HT942526TSCRPCTRA

Pre-Application Due: July 23, 2026

Application Due: August 6, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Support Center

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

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Tuberous Sclerosis Complex Research Program (TSCRP) Clinical Translational Research Award (CTRA) supports studies that will move promising, well-founded preclinical and/or clinical research findings closer to clinical application, including diagnosis, prognosis or treatment of tuberous sclerosis complex (TSC).

Distinctive Features: This funding mechanism allows for multiple Principal Investigators (PIs). Only the initiating PI will submit a pre-application, but all PIs will need to submit full applications. The partnering PI(s) application is an abbreviated package specific to their distinct portion of the research project. Be advised, all associated applications for a research project may be withdrawn if the initiating or partnering application is rejected or administratively withdrawn.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $3.50 million (M) to fund approximately two Clinical Translational Research Award applications with total cost caps of $1.60M for single PI applications and $1.90M for partnering PI applications. The maximum period of performance is **3** years. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), July 23, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, August 6, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, August 13, 2026
- **Peer Review:** November 2026
- **Programmatic Review:** February 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526TSCRPCTRA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

2.1.2. Principal Investigator

Independent investigators affiliated with an eligible organization are eligible to be named PI on the application, regardless of ethnicity, nationality or citizenship status.

Independent investigators at all career levels are eligible to be named as a PI, Initiating PI or Partnering PI.

Each investigator may be named on only one FY26 Tuberous Sclerosis Complex Research Program (TSCRP) CTRA application as a PI, Initiating PI or Partnering PI.

For studies that address improving clinical care of TSC, advanced practice providers, genetic counselors or nurses are eligible to be named as a PI, Initiating PI or Partnering PI.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Tuberous Sclerosis Complex Research Program (TSCRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the TSCRP in 2002 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the TSCRP from FY02 through FY24 totaled $121M. The TSCRP did not receive appropriation in FY25. The FY26 appropriation is $10M.

3.1. Award History

The TSCRP Clinical Translational Research Award mechanism was first offered in FY17. Since then, 36 Clinical Translational Research Award applications were received, and 13 were recommended for funding.

3.2. Intent of the CTRA

The CTRA supports studies that will move promising, well-founded preclinical and/or clinical research findings closer to clinical application, including diagnosis, prognosis or treatment of TSC. Projects supported by this award mechanism may include, but are not limited to:

- Studies moving from preclinical to clinical research and/or the reverse; or analyzing human anatomical substances and/or data associated with completed clinical trials to understand the mechanism of action, or to improve diagnosis, prognosis or treatment.
- Studies advancing clinical trial readiness through development of biomarkers, clinical endpoints and validation of pharmacokinetics/pharmacodynamics.
- Pilot clinical trials, where limited clinical testing (e.g., small sample size) of a novel intervention to produce information on diagnostic or therapeutic effectiveness, safety, tolerability or mechanisms of action. These studies should be aimed at obtaining preliminary data leading to the development of interventions with the potential to improve TSC outcomes.
- New studies improving clinical care of TSC encompassing the analysis of existing real-world clinical practice data to develop/improve guidelines for better outcomes in defined areas relevant to the FY26 TSCRP CTRA Focus Areas, include but are not limited to epilepsy surgery, tumor resection, reproductive health, perinatal surveillance and care, etc.

Preclinical studies may be appropriate but must include a clinical component. Projects that are strictly animal research will not be considered for CTRA funding and should consider other FY26 TSCRP funding opportunities.

3.2.1. Focus Areas for the CTRA

The FY26 TSCRP CTRA encourages applications in mechanistic studies, animal model development, biomarkers, therapeutics and patient-centered studies that address one or more of the following focus areas:

- Understanding, preventing and treating the features of TSC-Associated Neuropsychiatric Disorders and reducing their impact, including pharmacological, behavioral and surgical interventions.
- Strategies for preventing and eradicating tumors and cysts associated with TSC, such as angiomyolipomas, subependymal giant cell astrocytoma and lymphangioleiomyomatosis (LAM), including gaining a deeper mechanistic understanding of tumor microenvironment, TSC signaling and m-TOR independent pathways.
- Preventing epilepsy, improving treatment and mitigating neurodevelopmental and adverse outcomes associated with TSC-related seizures.
- Developing, assessing and testing emerging diagnostic and therapeutic technologies to improve outcomes in TSC.
- Understanding potential pathogenic mechanisms or improving outcomes of maternal-fetal and reproductive health of women with TSC or LAM and the perinatal care of fetuses or newborns with TSC.

3.2.2. Key Elements for the CTRA

The following are important aspects of the CTRA:

- **Translation:** The application should clearly state how the proposed research project will expand upon promising preclinical and/or clinical research findings to move the field closer to a clinical application by the end of the study.
- **Impact:** Proposed studies should have the potential to improve the diagnosis, prognosis, treatment of TSC or to improve clinical care of TSC by:
    - Likely having a major impact on TSC patients by applying promising and well-founded laboratory or other preclinical or clinical research findings to the care of patients.
    - Leveraging information from completed clinical trials to address knowledge gaps in resulting outcomes, validate key research findings and expand upon potentially transformative results, or investigate novel findings.
    - Developing or improving clinical care guidelines for better outcomes.
- **Feasibility:** The application should demonstrate that the investigators have access to the necessary specimens, data, intervention and patient population. If the application requires access to critical specimen or data, or if the application involves a pilot clinical trial, see Attachment 10, Letter(s) Confirming Access to Essential Resources.
- **Preliminary Data:** Unpublished results from the laboratory of the PI or collaborators named on the application, and/or data from the published literature that are relevant to TSC and the proposed research project, are required.
- **Partnering PI Option:** The TSCRP CTRA includes an option for more than one PI. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI, refer to Section 5.3, Submission Instructions.

3.2.3. Other Important Considerations for the CTRA

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

Clinical trials are allowed within this funding opportunity.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American Public. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

3.3. Funding Instrument

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

3.4. Funding Details

Period of Performance: The maximum period of performance is **3** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$1.60M** for single PI applications and **$1.90M** for partnering PI applications. 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.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Application Submissions With the Partnering PI Option: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI(s) should not exceed **$1,900,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

The applicants may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years. The duration of the period of performance for the Initiating PI and Partnering PI should be the same.

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

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

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

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the TSCRP Clinical Translational Research Award.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Pre-Application Components

The initiating PI must submit the following pre-application components:

Letter of Intent (one-page limit): Provide a brief description of the research to be conducted. Include the FY26 TSCRP CTRA Focus Area(s) or another important problem or unmet need in TSC research and/or patient care to be addressed.

Letters of intent (LOIs) are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT required after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

4.3. Full Application Components

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

Application submissions with the Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

4.3.1. Full Application Components for the PI or Initiating PI

Each application submission must include:

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

IMPORTANT: *When completing the SF424 R&R, enter the* ***eBRAP log number*** *assigned during pre-application submission into* ***Block 4a – Federal Identifier****.*

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (15-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.

  Describe the proposed project in detail using the outline below.

  - **Background/Scientific Rationale:** Present the ideas and rationale behind the proposed research project, including a well-formulated, testable hypothesis, and clear mechanistic underpinning. Include relevant literature citations. Describe previous experience and expertise most pertinent to the proposed research project. Inclusion of preliminary and/or published data that are relevant to TSC and the proposed research project are required.
  - **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.
  - **Research Strategy and Feasibility:**
    - Describe the experimental design and methods, including controls, sample size estimation, blinding, randomization and power analysis to achieve reproducible and rigorous results.
    - Address potential problem areas and present alternative methods and approaches.
    - Describe the handling, collection and analysis of data and ensure they are consistent with the study objectives.
    - Describe the statistical analysis plan appropriate for the proposed research project. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
    - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.
    - For applications proposing animal studies, describe how the animal studies are designed to achieve the objectives, including the choice of model(s) and endpoints/outcome measures to be used. Submission of Attachment 9, Animal Research Plan is required.
    - For clinical research or pilot clinical trial, 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, racial and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. The inclusion strategy should agree with the enrollment table(s) provided in Attachment 2, Supporting Documentation: Inclusion Enrollment Report.

- In addition, for applications involving data analysis and/or specimens from completed clinical trial(s) (including correlative studies):
  - Describe the proposed pre-existing cohort and its relevance to TSC, including the type of the data and/or specimens, and the size of the cohort. Submission of Attachment 10 is required to confirm the access to the necessary data and/or specimens.
- In addition, for applications involving a pilot clinical trial: (Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.)
  - Describe the type of pilot clinical trial to be performed, the intervention to be tested, human subject population to be recruited, outcome measures, ethical consideration, recruitment strategy and regulatory strategy, as appropriate. Submission of Attachment 10 is required to confirm the access to the intervention and patient population.

Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.

If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).

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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized form for this information.

Inclusion Enrollment Report *(only required if clinical research and/or a clinical trial 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. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific

individual, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

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 Support (five-page limit per letter is recommended): Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.

Sex as a Biological Variable (SABV) Strategy (two-page limit is recommended): Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

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.

Research Sharing Plan: Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or

their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan which will be requested only after a recommendation for funding is made.

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

Background: Present the scientific rationale behind the proposed research project.

Hypothesis/Objective(s): State the hypothesis to be tested and/or objective(s) to be reached.

Specific Aims: State the specific aims of the study.

Study Design: Describe the study design, including appropriate controls.

Military Relevance: Describe how the study is relevant to military health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

- Summarize the objectives and rationale for the proposed research.
- What population will the research help, and how will it help them?
- What are the potential applications, benefits and risks of the anticipated outcomes?
- What are the likely contributions of the proposed research project to advancing research, patient care and/or quality of life?
- What is the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families.

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

For guidance on preparing the SOW, refer to the Example: Assembling a Generic Statement of Work. Include milestones for data or research resource(s) sharing.

Partnering PI Option:

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

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".**

  Explain why the proposed research is important and the impact that it will have on one or more of the FY26 TSCRP CTRA Focus Areas. If the project does not address an FY26 TSCRP CTRA Focus Area, provide justification that the proposed research project addresses another important problem or unmet need in TSC research and/or patient care Explain the proposed research project's potential to improve the diagnosis, prognosis, or treatment of TSC by applying promising and well-founded laboratory or other preclinical or clinical research findings to the care of patients, and/or leveraging information from completed clinical trials to address knowledge gaps or investigate novel findings.

  - Short-Term Impact: Detail the anticipated outcome(s) that make an important contribution toward advancing TSC research.
  - Long-Term Impact: Explain the anticipated long-term gains from the proposed research project, including how the new understanding may ultimately contribute to the goal of advancing TSC research and/or patient care and make a significant contribution toward improving the diagnosis, prognosis or treatment of TSC.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **Attachment 7: Clinical Translation Statement (one-page limit): Upload as "Translation.pdf".**

  Describe the translational aspects of the proposed research. The ultimate goal of translational research is to move an observation forward into clinical application and accelerate the introduction of health care products, technologies or practice guidelines for clinical use. State explicitly how the proposed research project is translational in nature and describe how it will help to move an observation forward into clinical practice. If the proposed research includes both preclinical research and a pilot clinical trial, explain how the preclinical research and pilot clinical trial aims are connected and necessary to advance the research toward clinical implementation. Include a clear description of the next step in the translation of the results of this research after the end of the project.

- **Attachment 8: Partnership Statement (one-page limit): Upload as "Partnership.pdf"** ***(Attachment 8 is only applicable and required for applications submitted under the Partnering PI Option).***

  Describe the expertise of the Initiating and Partnering PIs and how each will bring different strengths to the proposed project. Describe the unique expertise that each PI brings to the project, how each is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts. Outline the contribution and time commitment of each partner and how each will have significant intellectual input on the design, conduct and analysis of the project. Describe how the PIs will manage the collaboration and workflow to optimize research efforts. Describe how the partners' combined experience will better address the research question and explain why the work should be done together rather than through separate efforts.

- **Attachment 9: Animal Research Plan (three-page limit): Upload as "AnimalPlan.pdf".** ***(Attachment 9 is only applicable and required for applications proposing animal studies.)***

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. 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 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.
  - 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 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 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 10: Letter(s) Confirming Access to Essential Resources: Upload as "Access.pdf".** ***(Attachment 10 is only applicable and required for applications involving data analysis and/or specimens or involving in a pilot clinical trial).***

  If applications are involved in analyzing data and/or specimens from completed clinical trials, provide a letter of support signed by the appropriate institution official who has the authority to confirm access to the proposed cohort data and/or specimens. If applications are involved in conducting a pilot clinical trial, provide a letter of support signed by the appropriate institution official who has the authority to confirm access to the proposed intervention and patient population.

- **Attachment 11: Representations** ***(Grants.gov submissions only)*****: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form** ***(if applicable)*****: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.


Grants.gov


eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s), or vice versa, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed budget information.

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*

4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*:

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Additional Application Materials:

The following are additional application materials for application submission. Follow the instructions specific to the submission portal found within the GAI.

Grants.gov eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI(s) should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed budget information.

iii. Project/Performance Site Location(s) Form

iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526TSCRPCTRA from Grants.gov or eBRAP, depending on which submission portal will be used.

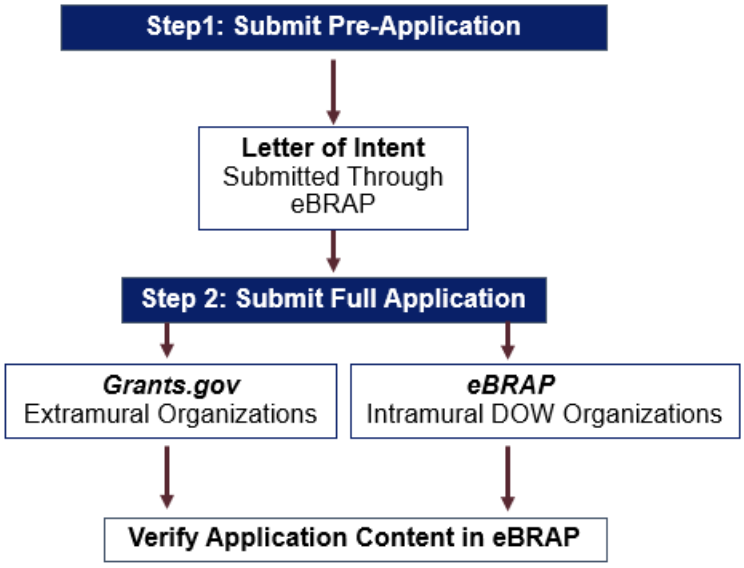
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP, including the submission of contact information for the Partnering PI if selecting the Partnering PI Option.

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. Contact the eBRAP Help Desk if any changes need to be made.

Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI(s) will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the instructions provided in the email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.
- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Single PI	Clinical Translational Research Award (CTRA)
Partnering PI Option	Clinical Translational Research Award – Partnering PI Option (CTRA-PPIO)

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

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.

Members of the FY26 TSCRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 TSCRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

Pre-applications submitted to this funding opportunity are used for program planning purposes only (e.g., reviewer recruitment) and will not be screened.

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, where **Clinical Translational Potential** is ranked as most important, **Impact** and **Research Strategy and Feasibility** are ranked as second most important, and all other scored criteria are of equal importance:

- **Clinical Translational Potential**
    - To what extent the proposed research project is translational in nature and will help to move an observation forward into clinical practice.
    - If the proposed research includes both preclinical research and a pilot clinical trial, to what extent the preclinical research and pilot clinical trial aims are connected and necessary to advance the research toward clinical implementation.
    - How well the application has described the next step in the translation of the results of this research after the end of the project.

- **Impact**
  - How well the proposed research project addresses one or more of the FY26 TSCRP CTRA Focus Areas or another important problem or unmet need in TSC research and/or patient care.
  - To what extent the proposed research project has the potential to improve the diagnosis, prognosis, or treatment of TSC by applying promising and well-founded laboratory or other preclinical or clinical research findings to the care of patients, and/or leveraging information from completed clinical trials to address knowledge gaps or investigate novel findings.
  - Assuming the objectives/goals of the proposed research project are realized:
    - To what extent the anticipated short-term outcomes will make an important contribution toward advancing TSC research.
    - To what extent the anticipated long-term outcomes will make a significant contribution toward improving the diagnosis, prognosis, or treatment of TSC.
    - To what extent the data and resources generated during the performance of the project will be shared with the research community.
- **Research Strategy and Feasibility**

  For all applications, the following criteria apply:
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and power analysis.
  - To what extent the statistical analysis plan is appropriate for the proposed research project.
  - How well the handling, collection, and analysis of data are consistent with the study objectives.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - If applicable, whether the strategy for the inclusion of women and minorities, and the distribution of proposed enrollment, are appropriate for the proposed research.
  - If applicable, how well the proposed animal studies are designed to achieve the objectives, including the choice of model(s) and endpoints/outcome measures to be used.
  - To what extent the proposed research project is feasible as described.
  - How well the application identifies potential problems and addresses alternative approaches.

  Additionally, for applications involving data analysis and/or specimens from completed clinical trial(s) (including correlative studies), the following criteria apply:
  - How well the application demonstrates access to the proposed pre-existing cohort specimens and/or data.
  - To what extent the proposed cohort is relevant to TSC.

Additionally, for studies including a pilot clinical trial, the following criteria apply:

- How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.
- How well the application demonstrates access to the study population, and ability to achieve recruitment goals.
- Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects.
- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity is included.
- For phase 3 clinical trials, whether the application describes plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity that are appropriate for the scientific goals of the study.

- **Rationale**
  - How well the scientific rationale, including a well-formulated, testable hypothesis and clear mechanistic underpinning, supports the proposed research project.
  - To what extent the provided preliminary data support the proposed research project.
- **Personnel**
  - To what degree the PI and research team's experience, expertise, and record of accomplishment demonstrate their ability to successfully complete the proposed research project.
  - How appropriate the levels of effort are for successful conduct of the proposed work.

For applications submitted under the Partnering PI Option:

- **Partnership**
  - How well the research project is supported by the nature of the collaboration.
  - To what extent the PIs' unique expertise, when combined as a partnership, will complement each other and better address the research question, rather than through separate efforts.
  - How well the application reflects the requirement that the partners have significant intellectual input into the design, conduct, and analysis of the project.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Budget**
  - Whether the budget is appropriate for the proposed research.
  - Whether the **total costs** exceed the allowable total costs as published in the program announcement.
- **Environment**
  - To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.

- How well the research requirements are supported by the availability of and accessibility to facilities and resources.

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

6.2.3. 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 peer reviewers
- Relevance to the priorities of the FY26 TSCRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact and clinical translational potential

6.3. Application Review and Selection Process

6.3.1. Pre-Application

There is no review and selection process for pre-applications submitted to this funding opportunity. ***The CDMRP will NOT provide an invitation to submit a full application after pre-application submission.*** Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

6.3.2. Full Application

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 subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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.

6.4. Risk, 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 the Code of Federal Regulations, Title 2, Part 200.1 (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 the SAM.

An applicant organization may review the 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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt and review process for the TSCRP 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

8. Post-Award Requirements

8.1. 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.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB or Ethics Committee (EC) review.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on ClinicalTrials.gov..

8.2. Reporting

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

Inclusion Enrollment Reporting: ***(only required for clinical research studies and clinical trials)***: Enrollment reporting on the basis of sex, race and/or ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

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

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the template available on the eBRAP “Funding Opportunities and Forms” web page under the “Progress Report Formats” section.

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 $10M are required to provide information to the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period

and that were connected with their 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.

8.3. Additional Requirements

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01d.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- The Project Narrative is missing.
- The Budget is missing.
- Pre-application was not submitted.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY26 TSCRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.

- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- Projects that are strictly animal research and do not include a clinical component.
- For projects involving data analysis and/or specimens from completed clinical trial(s) or involving in a pilot clinical trial, Attachment 10, Letter(s) Confirming Access to Essential Resource is missing.
- **Partnering PI Option:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- If an investigator is named in multiple FY26 TSCRP CTRA applications as a PI or partnering PI, only the first application(s) received will be accepted; additional applications will be administratively withdrawn.

9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Grants.gov submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(eBRAP 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"	☐	
Clinical Translation Statement – Attachment 7, upload as "Translation.pdf"	☐	
Partnership Statement – Attachment 8, upload as "Partnership.pdf"	☐	
Animal Research Plan – Attachment 9, upload as "AnimalPlan.pdf"	☐	
Letter(s) Confirming Access to Essential Resources – Attachment 10, upload as "Access.pdf"	☐	
Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Additional Application Materials		
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐	☐
Research & Related Budget	☐	☐
Project/Performance Site Location(s)	☐	☐
Research & Related Subaward Budget Attachment(s) (*if applicable*)	☐	☐

Appendix 2. Acronym List

CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTRA	Clinical Translational Research Award
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
SABV	Sex as a Biological Variable
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
TSC	Tuberous Sclerosis Complex
TSCRP	Tuberous Sclerosis Complex Research Program
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs