Program Announcement for the Defense Health Agency

Lupus Research Program
Transformative Vision Development Award

Funding Opportunity Number: HT942526LRPTVDA

Pre-Application Due: July 29, 2026

Application Due: August 19, 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: This funding mechanism supports planning and development activities and pilot studies that will generate preliminary data and demonstrate feasibility for achieving the aims of a future interventional study. Successful studies may be submitted to a future Lupus Research Program (LRP) Transformative Vision Award (TVA), or equivalent, for funding consideration (See Funding Opportunity Number HT942526LRPTVA for additional information). Research must address at least one of the fiscal year 2026 (FY26) LRP Transformative Vision Development Award (TVDA) focus areas. This funding mechanism allows for phase 0/1 clinical trials, if appropriate. The mechanism does not allow for phase 2/3 clinical trials or animal studies.

Distinctive Features:

- Preliminary data are permitted but not required.
- Applications ***must*** include at least one lupus consumer advocate as a member of the research team.
- An individual may be named as Principal Investigator (PI) on only one application per LRP award mechanism (Idea Award, Impact Award, TVDA, TVA), for a maximum of four applications to the FY26 LRP.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $500,000 to fund approximately two Transformative Vision Development Award applications with total cost caps of $250,000 per award. The maximum period of performance is 2 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 29, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, August 19, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, August 24, 2026
- **Peer Review:** October 2026
- **Programmatic Review:** February 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526LRPTVDA

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 (or equivalent) affiliated with an eligible organization are eligible to be named PI on the application, regardless of ethnicity, nationality or citizenship status. Individuals in mentored positions (e.g., postdoctoral fellows, clinical fellows, or equivalent) are not considered independent investigators and are not eligible.

An investigator may be named on only one FY26 LRP TVDA application as a 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 LRP. 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 LRP in 2017 to provide support for lupus research with high potential impact and exceptional scientific merit. Appropriations for the LRP from FY17 through FY24 totaled $65 million (M). The FY26 appropriation is $10M.

The LRP's vision is to cure lupus through partnership of scientists, clinicians, and persons affected by lupus. The LRP seeks to achieve this vision through its mission to fund research to understand, prevent, and diagnose lupus and to improve treatments and quality of life for patients, including Service Members and their Families, Veterans, and the general public.

Lupus is a complex disease that impacts multiple factors of an individual's life. Because of this, the LRP retains a broad research scope to ensure funding opportunities exist for any promising avenues of research with the potential to lead to improvements in treatments, patient quality of life, or lessening the severity of symptoms. The LRP welcomes applicants new to the field of lupus research with novel and innovative ideas for interventions that have the potential to make a significant impact in the lives of individuals with lupus. Applications may address the LRP focus areas in lupus patients of any age, including but not limited to those with disproportionate health burdens. The LRP encourages the use of computational methodologies, data science, and innovative technologies for biological, clinical data, and health care delivery.

3.1. Intent of the Transformative Vision Development Award

The LRP seeks to improve quality of life for individuals with lupus using an intervention at the individual and/or health care system level. This effort is supported through two related, but separate, award mechanisms, the LRP TVDA and the LRP TVA.

The TVDA supports planning and development activities and pilot studies that will generate preliminary data and demonstrate feasibility for achieving the aims of a future interventional study.

The related TVA supports applications that will fulfill an extraordinary vision for dramatically improving the quality of life of individuals with lupus in the near-term using an intervention at the individual and/or health care system level. Successful applicants to the TVDA may choose to submit a future application for funding consideration to a LRP TVA, or equivalent, as a next step. See Funding Opportunity Number HT942526LRPTVA for additional information.

Applicants are **not** required to be awarded a TVDA to submit a TVA application. Similarly, receipt of an FY26 LRP TVDA does **not** guarantee future funding for the proposed interventional study via a TVA or equivalent.

Examples of suitable FY26 LRP TVDA activities could include but are not limited to: optimizing an intervention, refining trial design, developing the clinical protocol, establishing access to appropriate patient populations or resources, planning for appropriate regulatory approvals, conducting feasibility or intervention safety studies, conducting development activities to support a future implementation research study, collecting informational data such as large scale data

mining, epidemiological studies or meta-analyses to inform a future interventional study, or developing a transition plan to facilitate rapid implementation and near-term impact.

Inclusion of preliminary data is not required.

3.2.1. Focus Areas for the TVDA

The proposed research **must** address at least one of the following FY26 LRP TVDA Focus Areas:

- Improving outcomes for lupus through innovative health care delivery models.
- Designing and implementing an intervention either at the individual and/or health care system level to improve the quality of life and mental health for individuals living with lupus. Example interventions include, but are not limited to, access to health care resources, outcomes research, symptom and disease control, comparative effectiveness research, and issues and challenges that, when addressed, make day-to-day living with lupus easier and life more fulfilling.

3.2.2. Key Elements for the TVDA

The following are important aspects of the LRP TVDA:

- **Impact:** The proposed research and future interventional study should have a major impact on the quality of life of lupus patients. Applications should clearly and explicitly describe the potential impact(s) of the proposed research and future interventional study for individuals living with lupus and convey its significance.
- **Research Strategy:** The scientific rationale and experimental methodology should demonstrate critical understanding and in-depth analysis of lupus. Applications may include experimental strategies that are novel or based on strong rationale derived from a literature review. Applicants need to propose appropriate development and/or pilot activities and explain how the research will support a future interventional study. Application must sufficiently describe the future interventional study to communicate the main aims of the research and reasoning for the currently proposed development and/or pilot research. Anticipated results should demonstrate feasibility of a proposed future interventional study.
- **Focus Areas:** The proposed research must address at least one of the FY26 LRP TVDA Focus Areas.
- **Research Team:** The research team's background should be appropriate with respect to its ability to successfully complete the proposed work.
- **Consumer Advocate:** The research team ***must*** include one or more lupus consumer advocate(s), who will be integral throughout the planning and implementation of the research project. Consumer advocates should be involved in the development of the research question, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. As lay representatives, the consumer advocates must be individuals who have been diagnosed with lupus or are caregivers, and they should be active in a lupus advocacy organization. Their role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. Their role should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, lupus. The consumer advocate(s) should have a high level of knowledge

of current lupus issues and the appropriate background or training in lupus research to contribute to the project.

- **Budget:** The proposed budget should be appropriate for the proposed research and within the limitations of this funding opportunity.

3.2.3. Other Important Considerations for the TVDA

Animal research is not allowed within this funding opportunity.

Phase 0/1 clinical trials (i.e., small proof-of-concept, pilot, or first-in-human trials to demonstrate feasibility or inform the design of more advanced trials) are allowed within this funding opportunity. Phase 2/3 clinical trials are not allowed. Applicants proposing phase 2/3 clinical trials should consider applying to the FY26 LRP TVA (HT942526LRPTVA). For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research, which is also 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 **2** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$250,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. 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 **2** years.

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

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

May be requested for:

- Phase 0/1 clinical trial costs.
- 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 FY26 LRP TVDA.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Animal research.
- Phase 2/3 clinical trial costs.

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

Pre-application submissions must include the following components.

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY26 LRP TVDA focus area under which the application will be submitted.

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.

(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 (seven-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below.

  - **Future Interventional Study:** Briefly describe the background and rationale for a future interventional study, clearly conveying how it will have a major impact by transforming the quality of life of individuals living with lupus. State the hypothesis(es) to be tested and/or the objective(s) to be reached, if funded. Concisely explain the specific aims of a future interventional study.
  - **Development Plan for TVDA:** Describe the work to be conducted during the FY26 LRP TVDA period of performance, clearly articulating how each task is necessary for and supports the initiation of a future interventional study.
    - **Background/Rationale:** Briefly describe the ideas and reasoning on which the proposed work is based. Demonstrate logical reasoning and provide a sound

scientific rationale for the proposed project as established through a critical review and analysis of published literature. Inclusion of preliminary data is encouraged but not required. If preliminary data are provided, it should support the feasibility of the work proposed. If preliminary data are not provided, anticipated results should demonstrate feasibility for a future interventional study. If proposing translational research, it is important to describe the studies showing proof of concept and clinical relevance.

- **Hypothesis(es) or Objective(s):** State the hypothesis(es) to be tested or the objective(s) to be reached.
- **Specific Aims:** Concisely explain the specific aims.
- **Research Strategy:**
  - Explain how the application develops and integrates the hypothesis(es) or objective(s), aims, experimental design, statistical and analyses into the project. The strategy for how sex will be considered as a biological variable should be provided as part of the application's Supporting Documentation (Attachment 2).
  - Describe how the experimental design and methodology are appropriate to address the stated objective(s), including how the proposed work supports a future interventional study. If the methodology is new or unusual, provide sufficient details for evaluation. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - Explain how the application acknowledges potential problems and addresses alternative approaches.
  - For applications proposing non-exempt clinical research or phase 0/1 clinical trials during the FY26 LRP TVDA period of performance, 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. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2). Refer to the CDMRP Directive on Inclusion of Women and Minorities as Subjects in Clinical Research for additional information.
  - Describe the availability of the necessary resources, including human subjects or human anatomical substances, as applicable, and include a sufficient plan for acquiring necessary research resources for the proposed project. 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.
  - **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 (two-page limit per letter is recommended):** Provide individual letters signed by collaborating individuals, including the consumer advocate(s), 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 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.
  - **Inclusion Enrollment Report *(only required if clinical research or a phase 0/1 clinical trial is proposed during the FY26 LRP TVDA period of performance)*:** 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.

- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations. Information regarding intellectual property can be found in the Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."
- **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.
  - **Focus Areas:** State which of the FY26 LRP TVDA focus areas will be addressed.

- **Hypothesis(es)/Objective(s):** State the hypothesis(es) to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including methodology, statistical analysis plan and appropriate controls. For clinical trials, state the type and phase of the trial, intervention being studied, and the primary projected outcome(s) of the trial.
- **Impact:** Summarize the near-term impact of this proposed TVDA research and the future interventional study on the quality of life of lupus patients of all ages and those with disproportionate health burdens.
- **Military Relevance:** Describe how the study is relevant to military health, including Service Members, their Families, Veterans and/or other DOW beneficiaries.

○ **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.
- Describe the relationship of the proposed work to the specific FY26 LRP TVDA focus area(s).
- Describe the ultimate applicability of this proposed TVDA research and the future interventional study.
  - What types of patients will the research help, and how will it help them?
  - What are the potential clinical applications, benefits and risks of the anticipated outcomes?
  - What is the projected time it may take to achieve a patient-related outcome?
  - What is the likely near-term impact of this proposed TVDA research and the future interventional study on the quality of life of lupus patients of all ages and those with disproportionate health burdens?
- What is the potential benefit of the proposed study and the anticipated outcomes to Service Members, their Families, Veterans and/or other DOW beneficiaries?

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

For guidance on preparing the SOW, refer to either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

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

- Clearly describe, in a manner readily understood by readers without a background in science or medicine, to what extent this proposed TVDA research and the future interventional study, if successful, will have a major near-term impact on the quality of life of lupus patients.

- Describe how this proposed TVDA research and future interventional study move beyond an incremental advancement compared to the current status of the field.
- Describe how the proposed research addresses at least one of the FY26 LRP TVDA focus areas.
- If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding lupus-related health differences between sexes.

- **Attachment 7: Personnel Statement (one-page limit): Upload as "Personnel.pdf".**
  - Explain how the research team's background is appropriate with respect to its ability to perform the proposed work, including evidence of sufficient clinical and/or statistical expertise (if applicable).
  - Explain how the levels of effort are appropriate for successful completion of the proposed work.
  - Provide the name of the consumer advocate(s) and their affiliation with a lupus advocacy organization(s). Describe the integral roles that the consumer advocate(s) will play in the planning, design, implementation, and evaluation of the research. A letter of support from each consumer advocate should be provided as part of the application's Supporting Documentation (Attachment 2).
- **Attachment 8: Clinical Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a phase 0/1 clinical trial are requested, this attachment is required.**
  - Describe the rationale for the proposed phase 0/1 clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe the type of phase 0/1 clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - If the proposed phase 0/1 clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source(s) of prior funding. Specifically, identify the portions of the study that would be supported with funds from this LRP TVDA award.
  - Provide detailed plans for initiating the clinical study within the first year, including U.S. Food and Drug Administration (FDA) Investigational New Drug/Investigational Device Exemption (IND/IDE) application submission plans within 60 days of the award, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
  - Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. A description of the strategy for inclusion of women and minorities appropriate to the objectives of the study should be provided as part of the application's Project Narrative (Attachment 1).
  - **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to

allow thorough evaluation of all statistical calculations during review of the application.

- **Attachment 9: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 10: 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		
iii. Project/Performance Site Location(s)		
iv. Research & Related Subaward Budget Attachment(s) *(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 HT942526LRPTVDA from Grants.gov or eBRAP, depending on which submission portal will be used.

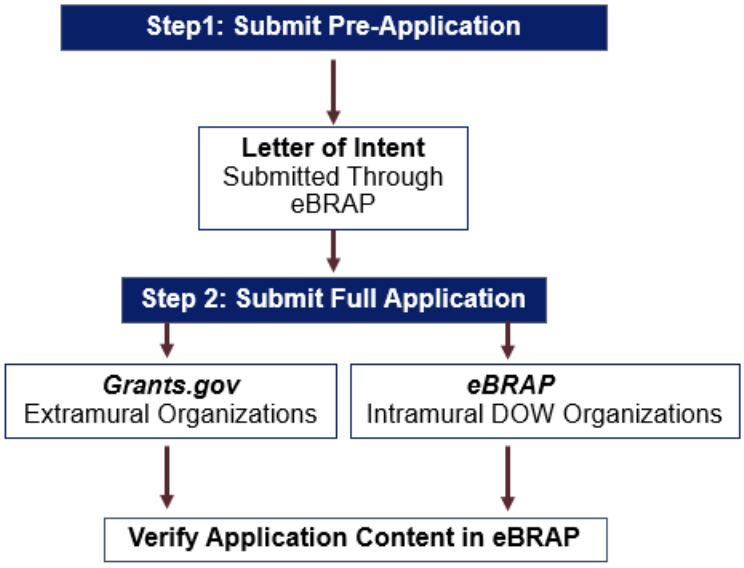
5.2. Unique Entity Identifier and System for Award Management

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 through eBRAP.

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.

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

Application Includes:	Select Mechanism Option:
No Clinical Trial	TVDA
Phase 0/1 Clinical Trial Option	TVDA-CT

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 LRP 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 LRP 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**, which are of equal importance:

- **Impact**
  - To what extent this proposed TVDA research and the future interventional study will have a major near-term impact on the quality of life of individuals living with lupus.
  - To what extent the proposed TVDA research and the future interventional study moves beyond an incremental advancement compared to the current status of the field.
  - How well the proposed research addresses at least one of the FY26 LRP TVDA Focus Areas.
  - If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding lupus-related health differences between sexes.

- **Research Strategy and Feasibility**
  - To what degree the proposed research is supported by a sound scientific rationale as demonstrated by a critical review and analysis of published literature and preliminary data (if included).
  - How well the application develops and integrates the hypothesis(es) or objective(s), aims, experimental design, methods, statistical plan and analysis into the project.
  - To what degree the experimental design and methodology are appropriate to address the stated objectives, including how the proposed research will generate feasibility data, if applicable, and support a future interventional study.
  - How well the application acknowledges potential problems and addresses alternative approaches.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.
  - As applicable, how well studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
  - Whether the application has provided sufficient evidence to support availability of and access to the populations/samples required for the study, and whether the plan for acquiring the necessary research resources is sufficient for the proposed research project (if applicable).
  - For applications proposing non-exempt clinical research or a phase 0/1 clinical trial during the FY26 LRP TVDA period of performance, the extent to which the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. 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.
- **Clinical Strategy (if application proposes a clinical trial)**
  - How well the phase 0/1 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 type of phase 0/1 clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
  - Whether the plan for applying for and obtaining the IND/IDE status (or other FDA or other international regulatory agency approvals) is appropriate, if applicable.
- **Personnel**
  - 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 clinical and/or statistical expertise (if applicable).
  - Whether the levels of effort are appropriate for successful completion of the proposed work.
  - How well the application describes the integral roles that the consumer advocate(s) will play in the planning, design, implementation and evaluation of the research.

- **Budget**
  - Whether the budget is appropriate for the proposed research.

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**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
- **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.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **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 LRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact

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. ***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 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 LRP 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 reorts 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 Institutional Animal Care and Use Committee (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

Quarterly and annual technical progress reports as well as a final technical progress report will be required. 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 ***(Required for research proposing clinical research and/or clinical trials)***: Enrollment reporting on the basis of sex, race and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on 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 $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.

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

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

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.
- The Project Narrative exceeds page limit.
- Pre-application was not submitted.
- The investigator is named as PI on more than one application submitted to the FY26 LRP TVDA. If applicants submit more than one FY26 LRP TVDA, the program will only accept the first submission and will administratively reject subsequent submissions.

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 LRP 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.
- The application does not address at least one of the FY26 LRP TVDA focus areas in Section 3.2.1.
- A phase 2/3 clinical trial is proposed.
- Animal research is proposed.
- The application fails to include at least one consumer advocate on the research team.

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.

9.3. Other Funding Opportunities

The LRP is committed to leveraging efforts with other funding organizations to accelerate progress in lupus research. At the time of funding notifications, the LRP will inform highly rated, unfunded applicants about opportunities to provide their LRP applications and peer review summary statements to non-governmental funders, who will determine the specific criteria for funding consideration.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
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"	☐
Personnel Statement – Attachment 7, upload as "Personnel.pdf"	☐
Clinical Strategy Statement ***(if applicable)*** **– Attachment 8, upload as "Clinical.pdf"**	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 9, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 10, 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
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
FDA	U.S. Food and Drug and Administration
FY	Fiscal Year
GAI	General Application Instructions
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Device
IRB	Institutional Review Board
LOI	Letter of Intent
LRP	Lupus Research Program
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
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
TVA	Transformative Vision Award

TVDA	Transformative Vision Development Award
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs