



## The Tau Pipeline Enabling Program IV (T-PEP)

### **Program Objective:**

Many devastating neurodegenerative disorders are associated with the abnormal build-up and/or spreading of the tau protein. These diseases are known as “tauopathies”. They include Alzheimer’s Disease (AD), Progressive Supranuclear Palsy (PSP), and other forms of frontotemporal dementia, among others. Tauopathies share the concept that synaptic loss, dendrite pruning and/or neuronal dysfunction are the most proximal events associated with the clinical expression of the dementia syndrome. As the field advances knowledge on the mechanisms of tau and related biological pathways (e.g., microtubule stability, inflammation, axonal transport, etc.), the potential to target tau and tau-related biological pathways emerges as a promising therapeutic strategy.

The **Tau Pipeline Enabling Program (T-PEP)** seeks to accelerate the discovery of potential new therapies for tauopathies. The intent of this program is to enrich the pipeline for therapy development by facilitating the translation of academia-derived ideas into practical application. In short, it bridges the gap between innovative but resource-constrained researchers and the larger pharmaceutical companies that are looking for drug candidates to be taken into human trials.

### **Program Overview:**

The overarching goal of T-PEP is to promote the advanced study of a wide range of novel targets, agents and/or therapeutic strategies that will accelerate the development of disease modifying interventions for tauopathies.

Proposals responding to this program may focus on the toxicity of tau directly and/or they may target their studies on potential neurobiological mechanisms that promote or synergize tau formation or toxicity, e.g., calcium dyshomeostasis, mitochondrial dysfunction, neuroinflammation, microtubule stability (or instability) and function, axon transport, synapse dysfunction/loss, and other tau-related mechanisms. Applications addressing related mechanisms must include the clear rationale that it will prevent, reduce, remove, or otherwise mitigate the toxic effects of tau build-up. **Funds awarded under this program must be used for lead optimization or IND-enabling studies, including cGMP scale-up/manufacture and animal efficacy studies.**

**Important to note: Prior T-PEP programs have included compound or target discovery; T-PEP 4 has narrowed the overall scope and focused on the specific aspects of the development pipeline noted above. Applications with a compound or target discovery component will be deemed unresponsive to this funding call**

T-PEP recognizes that the investigators who initially conceive of new therapeutic strategies are unlikely to possess the full range of expertise needed to independently advance their ideas through the drug discovery process. Accordingly, T-PEP encourages the use of interdisciplinary teams of academic collaborators, contract research organizations (CROs), and/or outside consultants who can assist in moving these projects forward.

T-PEP is open to researchers at academic institutions as well as small companies. There is no strict cut-off for company size, but preference will be given to companies with 50 or fewer employees. The maximum grant amount for non-profit academic institutions is \$750,000, with up to 10% indirect cost. The maximum grant amount for for-profit companies, with no indirect expenses allowed, is \$750,000. The maximum project duration is 2 years, and there is no minimum timeframe. As partners for this grant program, the Alzheimer's Association and the Rainwater Charitable Foundation will jointly monitor progress toward project milestones **Disbursement of funds will be contingent on demonstrated progress toward key milestones.**

### **Eligibility:**

Both non-profits and small for-profit organizations are eligible. For for-profits, preference will be given to companies with 50 or fewer employees. For-profits and non-profits must provide documentation verifying status. The Principal Investigator of the project must be a full-time faculty member or paid employee of the organization submitting the proposal. If the applicant is not a paid employee, they must demonstrate that they are part of the company and a listed employee. Applications from post-doctoral researchers will not be accepted. We encourage applications from teams led by women or investigators from underrepresented groups by scientist(s) from historically underrepresented teams, using the [NIH definition](#).

For questions about eligibility, please contact the Alzheimer's Association at [grantsapp@alz.org](mailto:grantsapp@alz.org).

### **Submitting a Letter of Intent:**

The Letter of Intent (LOI) is a required step in the application process. LOIs must be completed online at <https://proposalcentral.com>. First-time users must register and fill out a Professional Profile to begin the application process. No hard copies will be accepted.

### **Evaluation of LOIs:**

All LOIs will be evaluated prior to invitation. Only LOIs that meet program specific guidelines will be invited to submit full applications.

*LOIs will be reviewed by a panel of experts with special attention to:*

1. Alignment with the research priorities of the T-PEP Program as defined in this RFA
2. Scientific rationale, specific aims, and methodological rigor including a proposed timeline of the program
3. Potential impact of project on the prevention or treatment of tauopathies

4. Clear translation pathway from studies to clinical trials including identifying any collaborators that are intended to support the program

**Feedback will not be provided on LOIs that are not invited to submit a full application.**

**Submitting a Full Application:**

For those invited to submit a full application, additional materials will be required. Templates and instructions will be provided after LOI approval.

Full applications will include:

- Executive Summary (1 page)
- Work Plan (up to 5 pages, including goals/specific aims, methods and project plan); attention should be made to provide background addressing the link between target/ mechanism and human disease and a clearly defined therapeutic hypothesis regarding why strategy is expected to be successful
- Principal Investigator and Key Personnel *Curriculum Vitae* or Biosketch (no more than 4 pages per person)
- Gantt Chart of proposed project, including specific go/no-go milestones (up to 3 pages); this is required.
- Milestones – no upload – completed online and should be tied to specific budget components
  - The budget must be broken down into 6-month increments, with key milestones listed for each 6-month budget period
  - Milestones should align with your overall project goals and *be designed so it can be clearly determined if each one has been met*
  - For each milestone, indicate the relevant Project Aim of which it is a part
  - Next to each Project Aim, include the amount of budget allocated to that Aim
  - Example: Milestone 1 (Project Aim 1; \$50,000.00; 33% of Period 1 Budget)
- Available Resources and Budget Justification (2 pages)
  - If awarded, a full budget of planned expenses will be required.
  - Include a list of tools/models available (if appropriate, list critical tools and models to be used or needed in the course of the research)
  - No more than 10% indirects will be allowed for non-profits. No indirects will be allowed for for-profit entities.
  - Costs not allowed include:
    - Computer hardware or standard software (e.g. Microsoft Office, mouse monitor, computer parts)
    - Laboratory equipment such as freezers, ultracentrifuges, RT-PCR, Microscopy/imaging equipment
    - Service contract fees of equipment
    - Construction or renovation costs
    - Tuition
    - Rent for laboratory/office space
    - Expenses such as Data Network Recharges and Computing and communication device support services

- General liability insurances, such as GAEL
  - Wire and currency exchange fees
  - Salary and/or compensation for Alzheimer's Association Staff or current members of the Alzheimer's Association Medical and Scientific Advisory Group (MSAG) and the International Research Grant Program (IRGP) Council. A complete list of MSAG and IRGP Council members can be found on our website [alz.org/grants](http://alz.org/grants).
- Target Information
    - This attachment is required as part of the application.
    - Complete the table with all known information up to the point in development your compound is at.
  - Data Management and Sharing Plan
    - A complete Data Management and Sharing Plan is required as part of the application. We recommend using the provided amended NIH template.
    - When data sharing may be limited, applicants must explain such limitations at the time of application for grants within the submitted Plan.
  - Research Project Leadership Plan
    - Complete according to instructions contained on template form.

**Deadlines and Award Timeline:**

**Program will open for submissions on July 17, 2023.**

**Letters of Intent (LOI) must be received by 5:00 PM EST, August 30, 2023** Letters of Intent will not be accepted after this date. No exceptions will be made. All LOIs must be completed online at <https://proposalcentral.com>. No hard copies or emails will be accepted.

**Full Applications must be received by 5:00 PM EST, December 13, 2023.**

Applications will not be accepted after this date. No exceptions will be made. No hard copies or emails will be accepted. For any awarded grant, the Alzheimer's Association and Rainwater Charitable Foundation will issue a joint grant agreement. Applicants invited to submit a full application will receive a copy of this joint agreement prior to application deadline.

Every effort will be made to make award announcements by **February 29, 2024**.

**For More Information:**

Contact [grantsapp@alz.org](mailto:grantsapp@alz.org)

**The Tau Pipeline Enabling Program (T-PEP)**  
is jointly funded by the Alzheimer's Association and Rainwater Charitable Foundation