



The Tau Pipeline Enabling Program (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.

The formation or buildup and spread of tau protein is a common pathophysiological phenomenon associated with several different neurodegenerative disorders such as Alzheimer’s Disease (AD), Progressive Supranuclear Palsy (PSP), and Frontotemporal Dementia (FTD). Recent emerging knowledge about upstream biological events that precede or contribute to the formation of tau protein as well as growing knowledge about downstream consequences of tau toxicity now offer a rich array of novel ideas, targets and promising opportunities for therapy development.

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 rationale that it will prevent, reduce, remove or otherwise mitigate the toxic effects of tau build up. Funds awarded under this

program may be used for one or more steps in the drug discovery pipeline, including but not limited to i) assay development and high throughput screening, ii) lead optimization, and iii) IND-enabling studies, including related GMP scale-up/manufacture.

T-PEP recognizes that the world-class 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 is \$750,000. Non-profit academic institutions are allowed up to 10% indirect costs; no indirect costs are allowable for for-profit companies. Preference will be given to proposals where the institution contributes to the direct costs in a 1-for-2 match (one-third institution, two-thirds T-PEP). The maximum project duration is 2 years, and there is no minimum time frame. As co-sponsors of the grant program, the Alzheimer's Association and the Tau Consortium will jointly monitor progress toward project milestones; continued disbursement of funds may be made contingent on demonstrated progress toward key milestones.

Eligibility:

Both non-profit and small for-profit agencies are eligible. Preference will be given to for-profit 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. Applications from post-doctoral researchers will not be accepted. For questions about eligibility, please contact the Alzheimer's Association at 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.altum.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 of the proposed project
3. Potential impact of project on the prevention or treatment of tauopathies

Feedback is not 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)
- 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 decision steps
- Available Resources and Budget Justification (2 pages)
 - Expenses that will not be allowed under this award include tuition for full degree programs, rent for laboratory/office space, construction or renovation costs, facilities fees or laboratory/supply costs not directly relevant to the project. If awarded, a full budget of planned expenses will be required.
 - No more than 10% indirects will be allowed for non-profits. No indirects will be allowed for for-profit entities.

Deadlines and Award Timeline:

Letters of Intent (LOI) must be received by 5:00 PM EST, January 5, 2018. Letters of Intent will not be accepted after this date. No exceptions will be made. All LOIs must be completed online at <https://proposalcentral.altum.com>. No hard copies or emails will be accepted.

Full Applications must be received by 5:00 PM EST, March 2, 2018. Applications will not be accepted after this date. No exceptions will be made. No hard copies or emails will be accepted.

Award announcements will be made by **April 30, 2018**.

For More Information:

Contact grantsapp@alz.org

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