

### FRANK J. TUSA PILOT AWARD FOR RESEARCH IN HEPATIC ENCEPHALOPATHY 2025 REQUEST FOR APPLICATIONS

Issued September 1, 2024

### **AASLD Foundation's Mission:**

The American Association for the Study of Liver Diseases (AASLD) Foundation invests in innovative hepatology research and in the people who study and treat liver disease.

### **Grant Overview:**

The purpose of this award is to support new, highly innovative research ideas that focus on interventions to improve outcomes for persons living with Hepatic Encephalopathy (HE) from liver diseases. Responsive projects will address highly innovative research ideas that have a clear potential to produce high-impact results, but that have little or no preliminary data to successfully compete for funding from other sources. This award is not intended to support ongoing research in the applicant's laboratory, but rather support new ideas or approaches that have not previously been studied.

Who Can Apply: <u>Early-Stage Investigators</u> (as defined by the NIH) to Associate Professor Level Faculty

**Type:** Clinical, Translational, and Outcomes Research

**Award Term:** July 1, 2025 – June 30, 2026 (1 Year)

Award Amount: \$50,000

The application deadline for this award is **11:59 pm Eastern time**, **December 9**, **2024**. Applications received after the deadline will not be reviewed.

Funding for this award is made possible through the Frank J. Tusa Fund.

### **Key Dates:**

RFA Posted	Sep 1, 2024
Application Portal Opens	Sep 1, 2024
Application Deadline	Dec 9, 2024
Peer Review	Dec 2024 – Mar 2025
Earliest Notification Date	Apr 1, 2025
Earliest Funding Start Date	Jul 1, 2025

### **Research Objectives and Selection Criteria:**

AASLD Foundation is soliciting innovative, small-scale exploratory research grant proposals focused interventions to improve outcomes for persons living with Hepatic Encephalopathy (HE) from liver diseases. Funding is meant to allow investigators to test new ideas or methods to gather sufficient data to apply for longer-term grants. Projects must include direct clinical interaction (clinical), patient clinical data (outcomes), or patient samples (translational). Proposed research may include pragmatic studies.

Applicants will be evaluated based upon their background, their commitment to a career in hepatology research, the scientific merit of their research project and the environment in which they will conduct the project.

- Project feasibility, an appropriate environment to conduct the project, and relevant collaborators will strengthen the application.
- Work proposed must clearly be able to be accomplished in one year.
- Highly innovative, high-risk/high-reward projects will be prioritized.

Applications will be reviewed based on the written materials submitted. Incomplete applications and applications that fail to adhere strictly to the instructions (including the submission deadline and page limitations) will not be reviewed. All decisions are final.

### **Eligibility**

In order to be eligible for this award, the applicant must adhere to the following guidelines:

### 1. The applicant must:

- Be an Early-Stage Investigator (<u>as defined by the NIH</u>) up to faculty at or below the rank of Associate Professor/equivalent.
- Be a member of the American Association for the Study of Liver Diseases (AASLD) at the time of award application and maintain active membership for the duration of the award period.
- Be able to devote at least 20% effort to the research project on which this application is based.
- Be sponsored by a public or private non-profit institution accredited in the United States, Canada or Mexico engaged in health care and health-related research. Individuals employed at the NIH, FDA, and CDC are not eligible to apply.
- If the applicant is below the rank of Associate Professor/equivalent, they must have a mentor or comentor who is an AASLD member in good standing at the time of application and for the duration of the award period. Mentors are **not** required for Associate Professor/equivalent level applicants.
- Not hold federal funding (e.g., U, P, R, K, VA Merit, VA CDA) <u>unless</u> they are able to justify the following in their application:
  - i. The project is truly completely distinct and non-overlapping from existing funding.
  - ii. The proposed work cannot be completed using existing funds.

### 2. The proposed project must:

- Focus on research on interventions to improve outcomes for persons living with Hepatic Encephalopathy (HE) from liver diseases.
- Be hypothesis based.
- Include only 1-2 aims that can be completed in the one-year award term.
- Include direct clinical interaction (clinical), patient clinical data (outcomes), or patient samples (translational). Proposed research may include pragmatic studies.
- Not be an established project with alternate funding.
- Be conducted at the sponsoring institution within the United States, Canada, or Mexico.

### 3. Application limits:

- There is no restriction on the number of applicants an institution can sponsor each cycle, but only one applicant may be funded per distinct department within each institution in this award category.
- Applicants may only apply for one AASLD Foundation research award per calendar year.
- Eligible applicants in this category may also apply for the AASLD Foundation Advanced/Transplant Hepatology Award in the same calendar year.

### **Use of Funds:**

### **Total Award Amount: \$50,000**

• Award funds of \$50,000 will be provided in a single payment upon grant initiation.

Funds are unrestricted for direct project expenditures, except that equipment acquisition of \$5,000 or greater requires prior written approval from AASLD Foundation.

Pls will receive complimentary registration for The Liver Meeting during their one-year grant term.

No indirect costs, registration fees, or travel expenses are allowed.

How Award funds are allocated to allowable costs is at the discretion of the sponsoring institution. For example, while this award requires a minimum of 20% effort toward the funded research project, it is not required that PI salary must be directly supported by Foundation Award funds.

Unexpended funds at the end of the Award term must be promptly returned to AASLD Foundation.

### **Reporting Requirements:**

All reports to be provided by the PI for this award shall be in writing and acceptable to the Foundation as to the type of content and format. Failure by the PI to provide Research Progress or Fiscal Accountability Reports could jeopardize both the PI's and Institution's future eligibility to receive Foundation awards funding for other projects.

Written Report Type(s)	Reporting Period	Due to Foundation		
Final Research Progress Report and Fiscal Accountability Report	Jul 1, 2025 – Jun 30, 2026	Aug 31, 2026		

Pls are further required to attend virtual meetings to present information on their funded project to representatives of the Frank J. Tusa Fund as follows:

Virtual Presentation	Meeting Timeframe
Introductory Meeting and Project Overview	Aug 1, 2025 – Sep 30, 2025
Final Progress Report	Aug 1, 2026 – Sep 30, 2026

Pls will be responsible for promptly responding to requests from the Foundation for updates on their scientific accomplishments and participate in all efforts to track outcomes associated with this funding, including responding to annual post-award impact update surveys for up to five years following completion of their award.

Pls must also provide the Foundation with a digital copy of any published report of research sponsored in part or in full by the Foundation within one year of publication.

### **Intellectual Property:**

Applications for patents related to discoveries or inventions resulting from research during the award period will be subject to the policies of the Institution where the work is performed. However, the PI must notify the Foundation in advance of the intent to file such an application.

### **Application Resources:**

AASLD Foundation Research Award Glossary: www.aasldfoundation.org/glossary

Applicant FAQ: http://www.aasldfoundation.org/awardsFAQ

Previous Funding Programs Eligibility List: <a href="http://www.aasldfoundation.org/eligibility">http://www.aasldfoundation.org/eligibility</a>

NIH Biosketch Format: https://grants.nih.gov/grants/forms/biosketch.htm

NIH Other Support Format: https://grants.nih.gov/grants/forms/othersupport.htm

NIH PHS 398 Detailed Initial Budget Period Form: https://grants.nih.gov/grants/funding/phs398/phs398.html

### **Application Submission and Formatting:**

- 1. Assemble your application package in the order listed in the required documents section below.
  - Type responses where prompted and provide all requested signatures.
  - Include a header at the upper right corner of each page with your name (last name, first name) and award name.
  - Use half-inch margins. Do not use lettering smaller than 10 point.
  - Adhere to page limits and complete all sections.

Applications that do not meet the requirements, in content or format, will not be reviewed.

- 2. The completed application, letters of support or commitment, and other documents as applicable must be combined in the order listed in the Required Documents section below and submitted as one PDF document. Name the PDF file as follows: 2025 Tusa\_Last name, First name (Example: Tusa\_Smith, Jane)
- 3. Submit your application at <a href="www.liverresearchawards.org">www.liverresearchawards.org</a>. You will be sent an email confirmation that the application was received. If an email confirmation is not received in two (2) business days, please contact <a href="mailto:awards@aasld.org">awards@aasld.org</a> to confirm receipt.

Regu	ired Documents:						
		ed b	elow. Any additional documents (including letters of collaboration, additional				
	letters of recommendation, or documents that exceed the stated page limitations) will be removed from consideration.						
1	Cover Pages	•	Use pages 6-7 of this document as your application's cover pages.				
		•	Complete all information and include all required signatures. Signatures				
			may be digital, electronic, or "wet."				
2	Abstract	•	Provide your project's abstract using page 8 of this document.				
3	Resubmission	•	Complete page 9 of this document and include this with the cover pages.				
	Information and	•	If this application is a resubmission:				
	Original Reviewer		<ul> <li>Use the provided form to briefly describe how your resubmission</li> </ul>				
	Comments (if		responds to the issues and criticisms raised by reviewers in the				
	applicable)		original application. Also briefly describe any major additions,				
	, ,		deletions, or changes to the application.				
			o Include the original application's reviewer comments document.				
4	Biosketches	•	Limit five pages each				
		•	Provide a Biosketch in NIH format for the applicant, mentor, and any				
			other key personnel or other significant contributors/collaborators.				
5	Specific Aims	•					
	·	•					
			specific aims, and impact of the results.				
6	Research Plan	•					
		•	Prepare according to NIH guidelines: background, significance,				
			innovation, and approach.				
		•	The section on previous work should highlight the candidate's previous				
			studies and their contribution to knowledge in this field. (Appendices				
			should not be included.)				
		•	Inclusion of preliminary data is not required. This award is not intended to				
			support ongoing research in the applicant's laboratory, but rather support				
			new ideas or approaches that have not previously been studied.				
		•	Be specific with regard to:				
	<ul> <li>Why this project is novel and distinct from other ongoing work.</li> </ul>						
	<ul> <li>The applicant's plan to translate the Pilot Study into future</li> </ul>						
		federally funded grant applications.					
		Proposed work should be well defined and feasible within the fiduciary					
			and temporal limitations of the award (\$50,000 and 1 year respectively).				
7	Budget and	•	Using the NIH PHS 398 Detailed Initial Budget Period Form, show				
	Justification		proposed budget for use of \$50,000 AASLD Foundation Pilot funding				
			during the one-year award term.				
		•	<ul> <li>Equipment costs of \$5,000 or greater require specific justification.</li> </ul>				
		No additional or indirect costs, registration fees, or travel expenses are					
	allowed.						
		•	Provide a budget justification narrative to support the proposed budget.				

8	Research Facilities	•	Limit three pages  The research environment should be described, including access to patients, laboratory space (if applicable), consultants and technical				
			(including computer) resources.				
9	Research Support	•	Provide an accounting of all other institutional, federal and non-federal				
			support using the NIH "Other Support" form (link goes to direct				
			download).				
		•	Include all funding available from collaborators and sponsors.				
10	Letter(s) of	•	Limit one page each				
	Collaboration/Support	•	If applicable, letters of collaborative or mentoring arrangements that are				
	• •		significant to the proposal may be included.				
		•	Biosketches for significant contributors/collaborators should be included				
			as part of required documents section 4.				
11	Candidate's	•	Limit two pages				
	Statement	•	Statement should clearly describe the candidate's background, interest in				
			HE research and how HE-related investigation is or will be represented in				
			their overall research portfolio and impact on research career.				
12	Letter of Commitment	•	Limit one page				
	from Department	•	The Department Chair's letter should:				
	Chair		<ul> <li>Explicitly confirm the percent of available time that will be devoted to</li> </ul>				
			research activities on which this application is based during the award				
			(minimum 20%).				
			<ul> <li>Confirm and describe the institution's support of the candidate and</li> </ul>				
			commitment to their research success.				
13	Letter of	•	One letter, limit one page				
	Recommendation	•	If the applicant is below the rank of Associate Professor, the letter of				
			recommendation should be written by the applicant's mentor and				
			should explicitly confirm that the mentor has reviewed the full				
			research proposal prior to submission.				
		•	Letter should attest to the candidate's qualifications, commitment to				
			research and quality of scientific work, and the importance/potential				
			impact of the project.				
		•	If the mentor is also the department chair, the mentor can opt to submit				
			separate letters for required documents 12 and 13 or submit one				
			combined letter (2 page maximum) that clearly indicates dual role and				
			addresses points requested for both these required documents.				
14	Institutional Review	•	Use page 10 of this document to verify if IRB or IACUC approval is				
	Board (IRB) or IACUC		needed for this project.				
	Approval	•	If human or animal subjects are to be used, verification of IRB or IACUC				
			approval of the proposed research in the applicant's institution should be				
			provided prior to the award being granted.				
		•	IRB/IACUC approval (if necessary) must be applied for at the time of				
		L	application.				

The following pages contain forms that must be included in <u>all</u> applications. Please refer to the list of required documents above when assembling your final application package.

### Frank J. Tusa Pilot Award for Research in Hepatic Encephalopathy Application Cover Page Complete the form below and include the completed page as page 1 of your application package.

B 1 4 TW						
Project Title						
Applicant Name (last, first, middle initial)	AASLD Member Number					
Applicant Degrees(s)		Date of Terminal Degree (MM/YYYY)				
, ppilodin 20gi 000(0)		Date of Tollinia, Dogree (min, 111)				
Applicant Current Position Title		Appointment Date (MM/YYYY)				
Applicant Telephone	Applicant Ema	il				
Sponsoring Institution						
Sponsoring Division or Department						
openioning Errolet of Doparations						
Mentor Name (last, first, middle initial) (if applicant is below	rank of Associate Prof.)	AASLD Member Number (if applicable)				
Mentor Title (if applicable)	Mentor Institut	ion (if applicable)				
Mentor Telephone (if applicable)	Mentor Email (	Mentor Email (if applicable)				
Institution's Creek Administrator Name (lost first middle init	ial) Institution Figs	Let'l Co. Freed Office New York (but first with his 1979)				
Institution's Grant Administrator Name (last, first, middle init	institution Fisc	Institution Fiscal Officer Name, if different (last, first, middle initial)				
Institution's Grant Administrator Telephone	Institution Fisc	Institution Fiscal Officer Telephone				
Institution's Grant Administrator Email	Institution Fisc	Institution Fiscal Officer Email				
REQUIRED SIGNATURES	·					
NOTE: By signing below, you are certifying that t						
that Foundation guidelines do not allow for any in equipment, capital equipment except as noted; tr						
equipment, capital equipment except as noted, ti	avei, memberships and d	ides, subscriptions/books/periodicals, etc.).				
Applicant Signature	Name (Printed)	Date				
Mentor Signature (if applicant is below Associate Prof. Rank)	Name (Printed)	Date				
Department / Division Chair Signature	Name (Printed)	Date				
Institution's Grant Administrator Signature	Name (Printed)	Date				

### 2025 FRANK J. TUSA PILOT AWARD FOR RESEARCH IN HEPATIC ENCEPHALOPATHY ELIGIBILITY CHECKLIST

Complete the eligibility checklist below and include the completed page as page 2 of your application package.

1.	The applicant (select one):  ☐ Is at the Associate Professor/equivalent rank. ☐ Has a faculty appointment below the Associate Professor/equivalent level. ☐ Does not have a faculty appointment and is an Early State Investigator (as defined by the NIH) ☐ ESI: Date of terminal research degree or end of post-graduate clinical training (whichever is later)
2.	<ul> <li>The applicant confirms that (select all that apply):</li> <li>They are a member of the American Association for the Study of Liver Diseases (AASLD) at the time of award application and will maintain active membership for the duration of the award period.</li> <li>They will be able to devote at least 20% effort to the research project on which this application is based.</li> <li>They are sponsored by a public or private non-profit institution accredited in the United States, Canada or Mexico engaged in health care and health-related research.</li> <li>The proposed project will be conducted at the sponsoring institution within the United States, Canada or Mexico.</li> <li>If they are below the rank of Associate Professor, they have a mentor or co-mentor who is an AASLD member in good standing at the time of application and for the duration of the award period.</li> </ul>
3.	Projects with aims already funded by other awards will not be considered.  The applicant confirms that:  They <a href="have not">have not</a> held nor currently hold any awards for the project aims described in this proposal.  They <a href="have held">have</a> held or currently hold an award for the project aims described in this proposal.
4.	Applicants cannot hold federal funding (e.g. U, P, R, K, VA Merit, or VA CDA) unless they are able to confirm that: <ul> <li>The project is truly completely distinct and non-overlapping from existing funding;</li> <li>The proposed work cannot be completed using existing funds.</li> </ul>

# **ABSTRACT OF PROPOSED RESEARCH** In the box below, briefly describe the research project, technical approach and anticipated results. Include this page as page 3 of your application package. **RESEARCH INFORMATION**

## Current Percent Effort: Projected Under This Award: \_\_\_\_\_\_ Research \_\_\_\_\_\_ Research (this project) \_\_\_\_\_ Administration \_\_\_\_\_\_ Administration \_\_\_\_\_ Teaching \_\_\_\_\_\_ Clinical Activities \_\_\_\_\_ Teaching \_\_\_\_\_\_ Teaching

100%=Total 100%=Total

### **RESUBMISSION INFORMATION** Complete and include as page 4 of your application package. Is this application a resubmission to the AASLD Foundation awards program? ☐ No. ☐ Yes. If yes, briefly describe how your resubmission responds to the issues and criticisms raised by reviewers in the original application in the box below. Also briefly describe any major additions, deletions, or changes to the application. Attach the original reviewer comments following this page.

INSTITUTIONAL REVIEW BOARD (IRB)/ANIMAL CARE AND USE COMMITTEE (IACUC)
Complete this page and include it at the end of your application, with appropriate supporting documentation.

### **INSTITUTIONAL REVIEW BOARD**

A.	Does the proposed study require Institutional Review Board (IRB) approval?		Yes [	∃ No
В.	B. If the proposed study requires IRB approval, has the documentation verifying approval been included in the award application?		ained a	and
			Yes [	∃ No
	he proposed study has been approved, please provide documentation of verification with you nit 2 pages).	ır ap	plicati	on
lf I	RB approval is not necessary or not attached, please state why below:			
	ANIMAL EXPERIMENTATION			
A.	Does your proposed study involve the care and use of animals?		Yes [	∃ No
B.	If the proposed study involves the care and use of animals, has the proposed study been ap Institutional Animal Care and Use Committee (IACUC) of the applicant's institution and do the National Institutes of Health (NIH) Guidelines on the care and use of laboratory animals?		•	
	Tradional institutes of Fleath (Wiff) Culdelines on the care and use of laboratory animals:		Yes [	∃ No
C.	If the proposed study requires (IACUC) approval, has the documentation verifying approval and included in the award application?	beer	n obtai	ned
			Yes [	∃ No
	he proposed study involves the care and use of animals and has been approved by the Institute and Use Committee, please provide documentation of verification with your application (line)			
	approval by the Animal Care and Use Committee of the applicant's institution is not necessary ached, please state why below:	or r	not	
1				