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 these awards is to foster career development for individuals performing clinical research, translational research, or outcomes research in a liver-related area and who have shown commitment to excellence at an early stage of their research study. The award is intended to ensure that a significant portion of young investigators' time is protected for research, with an overall objective of enabling young investigators to develop independent and productive research careers in liver disease.

- Applications in health disparities-related research are encouraged.
- One award per year will be prioritized for meritorious transplant-related research in memory of the University of Michigan Transplant Team.

Who Can Apply: Junior Faculty Within 5 Years of First Appointment
Type: Clinical, Translational, and Outcomes Research
Award Term: July 1, 2024 – June 30, 2026 (2 Years)
Award Amount: $200,000 ($100,000/Year)

The application deadline for this award is **11:59 pm Eastern time, December 4, 2023**. Applications received after the deadline will not be reviewed.

Notice of Special Interest:

Additional dedicated funding to advance research activities in Autoimmune Hepatitis is available for the 2024 Awards cycle. Applications in autoimmune hepatitis are encouraged in all early to mid-career research award categories and the Pilot and Autoimmune Exploratory Research Award categories.

Key Dates:

RFA Posted	Aug 1, 2023
Application Portal Opens	Sep 1, 2023
Application Deadline	Dec 4, 2023
Peer Review	Dec 2023 – Mar 2024
Earliest Notification Date	Apr 1, 2024
Earliest Funding Start Date	Jul 1, 2024

Research Objectives and Selection Criteria:

AASLD Foundation is soliciting clinical, translational, and outcomes grant proposals focused on all aspects of liver diseases.

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.

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 within the first five years of their first faculty appointment (including prior appointments in universities outside of North America) at the start of the award (faculty appointment starting no earlier than July 1, 2019).
     - If the applicant does not have a faculty appointment at the time of application, the letter of commitment from their department chair must explicitly confirm that the applicant will have a faculty appointment (i) no later than the Award start date and (ii) for the full award cycle.
   - 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 50% 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.
   - Have a research 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.
   - Not hold/have held any other similar award that is intended to primarily support the salary of early career investigators (including but not limited to NIH R, P or most K level grants, or similar career development awards from federal or non-federal sources. See eligibility list for more common programs).

2. The proposed project must:
   - Be clinical (direct contact with patients, clinical trials), translational (investigation using patient samples), or outcomes-based (epidemiological studies, patient-centered outcomes, or health services) research.
   - 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.

Use of Funds:

Total Award Amount: $200,000
   - Award funds of $200,000 will be provided in quarterly installments of $25,000 over two (2) years ($100,000 per year).
   - Annual continuation of funding is contingent on the receipt and approval of annual progress and financial reports and continued adherence to Award eligibility and effort requirements. Continuation of annual funding is not contingent on specific research outcomes/results.

Funds may only be used for **PI salary support**, **technical support, laboratory supplies** (excluding capital equipment), and **limited travel support** for the recipient.
   - PI salary support or salary for technical support may include fringe.
   - Capital equipment is defined as items that cost $5,000 or greater, have a useful life of more than one year, and will not be expended or consumed in research.
   - PIs will receive complimentary registration for The Liver Meeting for the duration of their two-year grant term. Up to $2,000 of Award funding may be used for travel support only in the second/final year of the grant term to offset the PI's costs to attend The Liver Meeting and present an in-person progress update on their funded project to AASLD Foundation leadership.

No additional or indirect costs, registration fees, or travel expenses other than described above are allowed.

The AASLD Foundation does not require, nor does it approve, a detailed project budget for this award category. Budget proposals submitted by PIs to their institution's sponsored projects office that allocate Award funds to unallowable costs should not be considered approved by AASLD Foundation. The sponsoring institution is responsible for ensuring that Award funds are only used for allowable costs.

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 50% effort toward the funded research project, it is not required that PI salary must be directly supported by Foundation Award funds. It is expected that additional institutional funds will be available to the investigator to carry out the proposed research.

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 Types(s)	Reporting Period	Due to Foundation
Year 1 Interim Research Progress Report and Fiscal Accountability Report	Jul 1, 2024 – Mar 30, 2025	May 1, 2025
Year 2 Final Research Progress Report and Fiscal Accountability Report	Apr 1, 2025 – Jun 30, 2026	Aug 31, 2026

PIs are further required to present an in-person progress update to AASLD Foundation leadership on their funded project in their second/final year of funding at an event held annually during The Liver Meeting.

PIs 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.

PIs 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: http://www.aasldfoundation.org/eligibility
NIH Biosketch Format: https://grants.nih.gov/grants/forms/biosketch.htm
NIH Other Support Format: https://grants.nih.gov/grants/forms/othersupport.htm

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: 2024 CTORA_Last name, First name (Example: 2024 CTORA_Smith, Jane)

3. Submit your application at www.liverresearchawards.org. 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 awards@aasld.org to confirm receipt.

Required Documents:

Submit only the documents listed below. 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 Information and Original Reviewer Comments (if applicable)**	- Complete page 9 of this document and include this with the cover pages. - If this application is a resubmission: - Use the provided form to briefly describe how your resubmission responds to the issues and criticisms raised by reviewers in the original application. Also briefly describe any major additions, deletions, or changes to the application. - 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**	**Limit one page** - State the proposed project's overall research hypothesis, objectives, specific aims, and impact of the results.
6	**Research Plan**	**Limit eight pages, <u>not including references</u>** - 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.)
7	**Project Timeline and Milestones**	**Limit one page** - Describe goals and timeline for completion of project milestones. - Proposed work must clearly be able to be accomplished in the award term (2 years).

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 Collaboration/Support	• **Limit one page each** • 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 Statement	• **Limit two pages** • Provide a career development plan that includes your background, short/long term goals, plan for career development/training activities during award, and the impact receiving this award would have on your research career.

12	Letter of Commitment from Department Chair	• **Limit one page**
		• The Department Chair's letter should:
		  o Explicitly confirm the percent of available time that will be devoted to research activities on which this application is based during the award (minimum 50%).
		  o Confirm and describe the institution's support of the candidate and commitment to their research success.
		• If the applicant does not have a faculty appointment at the time of award application, the letter must explicitly confirm that the applicant will have a faculty appointment (i) no later than the Award start date and (ii) for the full award cycle.

13	Mentor Letter of Recommendation	• **One letter, limit one page**
		• The Mentor's letter should:
		  o Confirm and describe their personal support of the candidate and commitment to their success.
		  o Explicitly state that they have reviewed the full research proposal prior to submission.
		  o Attest to the candidate's qualifications, commitment to research and quality of scientific work.
		• If the mentor is also the department chair, they 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	One additional Letter of Recommendation	• **Limit one page** • Letter should attest to the candidate's qualifications, commitment to research and quality of scientific work.
15	Institutional Review Board (IRB) or IACUC Approval	• **Use page 10 of this document to verify if IRB or IACUC approval is needed for this project.** • 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 application.

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

2024 CLINICAL, TRANSLATIONAL, & OUTCOMES RESEARCH AWARD (CTORA) APPLICATION COVER PAGE

Complete the form below and include the completed page as page 1 of your application package.

Project Title	
Applicant Name (last, first, middle initial)	AASLD Member Number
Applicant Degrees(s)	Date of Terminal Degree (MM/YYYY)
Applicant Current Position Title	Appointment Date (MM/YYYY)
Applicant Telephone	Applicant Email
Sponsoring Institution	
Sponsoring Division or Department	
Mentor Name (last, first, middle initial)	AASLD Member Number
Mentor Title	Mentor Institution
Mentor Telephone	Mentor Email
Institution's Grant Administrator Name (last, first, middle initial)	Institution Fiscal Officer Name, if different (last, first, middle initial)
Institution's Grant Administrator Telephone	Institution Fiscal Officer Telephone
Institution's Grant Administrator Email	Institution Fiscal Officer Email

REQUIRED SIGNATURES

NOTE: By signing below, you are certifying that the information in this application is accurate and that you understand that Foundation guidelines do not allow for any indirect costs (e.g., facilities management and utilities; general-purpose or capital equipment; travel except as noted; memberships and dues; subscriptions/books/periodicals; etc.).

Applicant Signature	Name (Printed)	Date

Mentor Signature	Name (Printed)	Date

Department / Division Chair Signature	Name (Printed)	Date

Institution's Grant Administrator Signature	Name (Printed)	Date

2024 CLINICAL, TRANSLATIONAL, & OUTCOMES RESEARCH AWARD (CTORA) ELIGIBILITY CHECKLIST
Complete the eligibility checklist below and include the completed page as page 2 of your application package.

1. The applicant:
   - ❑ Is a junior faculty member (at or below the rank of Assistant Professor for no more than five years at the start of the award / faculty appointment starting no earlier than July 1, 2019.
     Faculty Start Date: _____
   - ❑ Has a faculty appointment that will start on or prior to the award start date.
     Anticipated Faculty Start Date: _____

2. The applicant confirms that (select all that apply):
   - ❑ 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.
   - ❑ They will be able to devote at least 50% effort to the research project on which this application is based.
   - ❑ 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.
   - ❑ The proposed project will be conducted at the sponsoring institution within the United States, Canada or Mexico.
   - ❑ 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.

3. Applicants cannot hold other similar research awards that are intended to primarily support the salary of early career investigators, including but not limited to NIH R, P or most K level grants, or similar career development awards from federal or non-federal sources (See eligibility list for more common programs).

   The applicant confirms that:
   - ❑ They **have not** held nor currently hold any similar research awards.
   - ❑ They **have** held or currently hold a similar research award.

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:

_____ % Research
_____ % Administration
_____ % Clinical Activities
_____ % Teaching

100%=Total

Projected Under This Award:

_____ % Research (this project)
_____ % Research (other)
_____ % Administration
_____ % Clinical Activities
_____ % Teaching

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. <u>Attach the original reviewer comments following this page</u>.

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

B. If the proposed study requires IRB approval, has the documentation verifying approval been obtained and included in the award application?

☐ Yes ☐ No

If the proposed study has been approved, please provide documentation of verification with your application **(limit 2 pages)**.

If IRB 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 approved by the Institutional Animal Care and Use Committee (IACUC) of the applicant's institution and do they follow the National Institutes of Health (NIH) Guidelines on the care and use of laboratory animals?

☐ Yes ☐ No

C. If the proposed study requires (IACUC) approval, has the documentation verifying approval been obtained and included in the award application?

☐ Yes ☐ No

If the proposed study involves the care and use of animals and has been approved by the Institutional Animal Care and Use Committee, please provide documentation of verification with your application **(limit 2 pages)**.

If approval by the Animal Care and Use Committee of the applicant's institution is not necessary or not attached, please state why below: