

REQUEST FOR APPLICATIONS

AASLD FOUNDATION

CLINICAL, TRANSLATIONAL, AND OUTCOMES RESEARCH AWARD IN LIVER DISEASES (CTORA)

Application Deadline: December 3, 2020

Award Period: July 1, 2021 – June 30, 2023 (2 Years)

Award Amount: \$200,000 (\$100,000/Year)

AASLD Foundation's Mission

To invest in innovative hepatology research and in the people who study and treat liver disease.

Award Description

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.

One award per year will be reserved for meritorious transplant-related research in memory of the University of Michigan Transplant Team.

Special RFA for Hepatorenal Syndrome 1 (HRS-1) Related Research

Dedicated funding is available for the 2021 awards cycle to support one highly meritorious project focused on Hepatorenal Syndrome 1 (HRS-1) related research.

Application Submission

The application deadline for this award is **11:59 pm Eastern time**, **December 3**, **2020**. Applications received after the deadline will not be reviewed.

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.

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.

Award Details

- Awards of \$200,000 will be provided over two years (\$100,000 per year).
- Funds may only be used for **salary support** and/or for **technical support/laboratory supplies** (excluding capital equipment) for the recipient.
- **No indirect costs, registration fees, or travel expenses are provided.** It is expected that additional funds are available to the investigator in order to carry out the proposed research.
- Awards cannot be transferred to another institution without prior written approval from AASLD Foundation.
- Funding notifications for the 2021 awards cycle will be sent no later than May 1, 2021.

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 (5) years of his/her first faculty appointment (including prior appointments in universities outside of North America) at the start of the award (July 1, 2021).
 - i. If the applicant does not have a faculty appointment at the time of application, a letter signed by the department chair confirming that the applicant will have a faculty appointment (i) no later than the Award start date and (ii) for the full award cycle must be submitted.
- 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.
- 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.
- Not hold other similar research awards. Applicants who hold other research awards (including but not limited to NIH K08, K23, R21; Veterans Administration Merit Review Grant or Career Development Award; AGA Research Scholar Award; Glaxo Institute of Digestive Health Award; American Liver Foundation Liver Scholar Award, etc.) are not eligible.

2. The proposed project must:

- Be clinical, translational, or outcomes-based research. "Clinical Research" is defined as studies related to
 patients or disease processes having direct contact between the principal investigator and humans.
 Clinical research includes clinical trials in liver disease. "Translational Research" is defined as clinical
 research with a substantial component of laboratory investigation using blood or tissue specimens from
 patients with liver disease. "Outcomes Research" includes epidemiological studies, patient-centered
 outcomes research or health services research.
- Be conducted at the sponsoring institution within the United States, Canada or Mexico.

3. Application limits:

- A single sponsoring institution may submit up to two applications per distinct department within each institutional training site.
- Applicants may only apply for one (1) AASLD Foundation (AASLDF) award per application cycle.

Selection Criteria

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.

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

Research Award Glossary

Clinical Research: Studies related to patients or disease processes having direct contact between the principal investigator and humans. Clinical research includes epidemiology and clinical trials in liver disease.

Collaborator: An individual who works with the principal investigator in the scientific development or execution of the project. This individual would typically devote a specific percent of effort to the project and would be identified as key personnel. The collaborator may be employed by or affiliated with either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

Grant Administrator: The staff member who oversees new grant agreements and grant payments; ensure that grants comply with relevant laws and regulations; guarantees that all required reports are submitted; and administers the grant after award.

Indirect Costs: Costs that are necessary to support a particular activity project or program but that cannot be easily or directly attributed to such activity, project or program. Examples of indirect costs are rent, utilities, and administrative personnel.

Junior Faculty: Faculty at or below the rank of Assistant Professor for no more than five years at the start of the award.

Mentor: Senior professional who provide guidance, direction and support to the applicant. This person should have a vested interest in the career development and research experience of the applicant.

Outcomes Research: Includes epidemiological studies, patient-centered outcomes research or health services research.

Standard Form 424 (Research & Related) Biosketch and NIH Guidelines: Biosketch and NIH Guidelines: The SF424 (R&R) biosketch is the application form used to obtain federal grant support. According to NIH guidelines, the research plan should contain: title, specific aims, significance, innovation, and approach. To access the biosketch via the Web, go to https://grants.nih.gov/grants/forms/biosketch.htm and select the non-fellowship Biographical Sketch Format Page.

Translational Research: Clinical research with a substantial component of laboratory investigation using blood or tissue specimens from patients with liver disease.

Application Instructions

- 1. Use pages 6-7 of this application as cover pages. Print or type responses.
- 2. Include only the required documents and provide signatures as requested.
- 3. Put your name (last name, first name) and the name of the award in the upper right-hand corner of each page.
- 4. Use half-inch margins. Do not use lettering smaller than 10 point.
- 5. Be sure to adhere to page limits and complete all sections. Applications that do not meet the requirements, in content or format, will not be reviewed.
- 6. Assemble the application package as a single PDF in the order listed in the Required Documents section (pages 4-5).
- 7. The completed application, letters of support or commitment, and other documents as applicable must be combined into and submitted as one PDF document. Name the PDF file as follows: 2021 CTORA Last name, first name (Example: 2021 CTORA Smith, Jane)

Required Documents

Submit only the documents listed below, using pages 6-7 as cover pages. 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 RFA as your application's cover pages.				
•	Cover rages	Complete all information and include all required signatures.				
		Signatures may be digital, electronic, or "wet."				
2	Abstract	Provide your project's abstract on page 8 of this application.				
3	Resubmission					
3	Information	 Complete page 9 of this application and include with cover pages. Use the provided form to briefly describe how your resubmission responds to the 				
	IIIIOIIIIatioii	issues and criticisms raised by reviewers in the original application. Also briefly				
		describe any major additions, deletions, or changes to the application.				
4	Applicant's and	Limit five pages each				
7	Mentor's Biosketch	 Limit five pages each Provide a biographical sketch for the applicant and mentor using the current SF424 				
	Weiltor 5 Dioskettii	From (see glossary).				
5	Research Plan	Limit eight pages, including references				
	Research Flan	Prepare according to NIH guidelines: title, specific aims, significance, innovation,				
		and approach.				
		The section on previous work should highlight the candidate's previous studies and				
		his/her contribution to knowledge in this field. (Appendices should not be				
		included.)				
9	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.				
10	Research Support	Accounting of all other institutional, federal and non-federal support is required.				
		The NIH "Other Support" form (link goes to direct download) should be used and is				
		available through academic institutions' Office of Grants and Contracts.				
		Include all funding available from collaborators and sponsors.				
11	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.				
12	Candidate's Statement	Limit one page				
		Describe the benefits of this award to your research career and, where applicable,				
		the impact the research preceptor will have on your research development.				
13	Letter of Commitment	Limit one page				
	from Department	Letter should be provided from the head of the candidate's department explicitly				
	Chair	confirming that a minimum of 50% of the available time will be devoted to research				
		activities on which this application is based during the award.				
		Letter should 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 Department Chair letter must confirm that the applicant will have a				
		faculty appointment (i) no later than the Award start date and (ii) for the full award				
		cycle.				

14	Letters of	Two letters, limit one page each			
	Recommendation	One letter must be from the applicant's mentor.			
		• Letters should attest to the candidate's qualifications, commitment to research and quality of scientific work should be submitted with the application.			
		The mentor's letter should confirm and describe their personal support of the			
		andidate and commitment to their success.			
15	Institutional Review	Use page 10 of this application to verify if IRB approval is needed for this			
	Board (IRB)	project.			
		If human subjects are to be used, verification of IRB 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 <u>all</u> applications. Please refer to the list of required documents above when assembling your final application package.

APPLICATION FOR THE 2021 CLINICAL, TRANSLATIONAL, AND OUTCOMES RESEARCH AWARD IN LIVER DISEASES (CTORA)

Applicant (last, first, middle initial)	AASLD Memb	er Number
Project Title		
Degree(s) and year(s) granted		
Current Position	Appointment	Date (month & year)
Address		
Telephone	Email	
Sponsoring Institution		
Mentor (last, first, middle initial)	AASLD Memb	er Number
Address		
Telephone	Email	
Institution's Grants Administrator		
Grants Administrator's Address		
Grants Administrator's Phone	Grants	s Administrator's Email
Institution Fiscal Officer, if different (please print)		
Required Signatures NOTE: By signing below, you are certifying that the inf guidelines do not allow for any indirect costs (e.g. facili memberships and dues; subscriptions/books/periodica	ties management and utilities; gen	
Signature of Applicant	Name	Date
Signature of Mentor	Name	Date
Signature of Department Chair	Name	Date
Signature of Grants Administrator	Name	Date

2021 AASLD FOUNDATION CLINICAL, TRANSLATIONAL, AND OUTCOMES RESEARCH AWARD IN LIVER DISEASES (CTORA) ELIGIBILITY CHECKLIST

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

1.	e applicant: Is a junior faculty member (at or below the rank of Assistant Professor for no more than five years at the start the award); or Has a faculty appointment that will start on or prior to the award start date. Infirm the applicant's actual or anticipated faculty start date:	of
2.	e 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 Me engaged in health care and health-related research. The proposed project will be conducted at the sponsoring institution within the United States, Canada or Mex 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.	ico
3.	plicants cannot hold other similar research awards. Applicants who hold other research awards (including but no hited to NIH K08, K23, R21; Veterans Administration Merit Review Grant or Career Development Award; AGA search Scholar Award; Glaxo Institute of Digestive Health Award; American Liver Foundation Liver Scholar Award; are not eligible. Example 2.) are not eligible.	
	They <u>have not</u> held nor currently hold any similar research awards. They <u>have</u> held or currently hold a similar research award.	
n (TIONAL FUNDING OPPORTUNITIES efforts to fund more high-impact proposals, AASLD Foundation seeks partnerships with individual or private ation donors that have expressed interest in supporting research projects in specific diseases or areas of focus.	
nd	indicate below if you give AASLD Foundation permission to share your de-identified application with potential ual or private (non-industry/corporate) foundation donors in the event your application is highly meritorious ares with one of these opportunities.	ıd
	Yes, I agree to allow AASLD Foundation to share my de-identified application with potential individual donors private (non-industry/corporate) foundations that have an interest in supporting research in my area of focus. No, I do not agree to allow AASLD Foundation to share my de-identified application with any potential private donors.	

Abstract of Prop In the box below, briefly of your application pack	describe the research projec	ct, technical approach and anticipated results. Include this page as	ıs page .
Research Informati	ion		
Current Percent Effo		Projected Under This Award:	
	_ Research _ Administration	Research Administration	
	_ Clinical Activities _ Teaching	Clinical Activities Teaching	
100%=Total		100%=Total	

Resubmission Information

original application application.	n in the box below.	Also briefly desc	ribe any major ad	ditions, deletions,	or changes to th
аррпсацоп.					

INSTITUTIONAL REVIEW BOARD (IRB)

Complete this page and include it at the end of your application, with appropriate supporting documentation.

IRB approval (if necessary) must be applied for at time of award application.

INSTITUTIONAL REVIEW BOARD

A.	Does the proposed study require Institutional Review Board (IRB) approval?	□ Yes □ No		
В.	If the proposed study requires IRB approval, has the documentation verifying approval been the award application?	obtained and included i		
	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:				