ACG CLINICAL RESEARCH AWARDS

2024 HEALTH EQUITY RESEARCH AWARDRequest for Applications

This is a two-year clinical research award for physicians to support health equity research in gastroenterology or hepatology.

METABLINE: MONDAY, DECEMBER 4, 2023, AT 11:59 PM EDT

◆ APPLY: gi.org/research-awards

Award Amount: up to \$75,000 (50k year-one, 25k year-two, based on progress) (requires preliminary data)

Award period/length of award: July 1, 2024 - June 30, 2026

The American College of Gastroenterology recognizes the importance of equity in health and healthcare. We believe that everyone should have a fair and just opportunity to achieve their full health potential. Unfortunately, many digestive diseases disproportionately burden certain minority groups, highlighting significant disparities in their evaluation, management, and clinical outcomes. Accordingly, the ACG Institute identified a critical need to offer targeted research funding to produce actionable science that will translate to reducing health and/or healthcare disparities, thereby promoting health equity. We invite eligible applicants to apply for a \$75,000 two-year (50k for year-one and 25k for year-two, based on progress) research award, to be funded from July 1, 2024 - June 30, 2026.

All applications must be submitted online. The grant site will open to submissions on September 5, 2023, and close on Monday, December 4, 2023 at 11:59pm (Eastern time).

The goal of the Health Equity Research Award is to support promising investigators in developing research careers that have a direct bearing on clinical gastrointestinal practice by advancing our knowledge in reducing disparities in the care and outcomes of racial/ethnic minorities, women, LGBTQ+ populations, and/or those living with a disability that is not derivative of a gastrointestinal disease, within the broader context of gastrointestinal and liver diseases. For this RFA a disability is defined as a physical or mental impairment that substantially limits one or more major life activities.

This grant is designed to support patient-oriented research that is principally focused on digestive or liver diseases. The patient population or disease target should be principally related to the gastrointestinal tract, liver, biliary system, pancreas, or neuroenteric science. We are interested in funding clinical, translational, social science, or health services research studies that aim to accelerate our clinical knowledge in managing the unique GI and hepatology healthcare concerns of underrepresented racial/ethnic minorities, women, LGBTQ+ populations, and/or those living with a disability., and potential to reduce health disparities. (For questions on study relevancy, contact the grant administrator at research@gi.org.) Since its inception in 1994, the ACG Institute has provided over \$29 Million in funding for Clinical Research Awards to over 721 recipients.







GRANT OVERVIEW

A key mission of the ACG and its Institute for Clinical Research and Education is to fund innovative patient-oriented research awards. For the purposes of these awards, patient-oriented research is defined as:

- 1. Research conducted with human subjects
- 2. Research on new diagnostic and therapeutic interventions
- 3. Research on material of human origin, such as tissues and specimens
- 4. Research that is translational in nature; i.e., has direct applicability to clinical care

Note: Studies involving animals will not be considered unless the work cannot be done in humans.



The ACG Clinical Research Awards are a project of the ACG Institute and are supported by charitable contributions to the ACG's ongoing fundraising campaign - The G.U.T. Fund.

✓ ACG Membership Requirement:

*Important! The Principal Investigator must be an ACG member in good standing. Applicants awaiting final approval of their applications are ineligible. ACG membership must be active no later than October 2023. To Join ACG, <u>click here</u>. For questions on ACG membership, please email <u>membership@gi.org</u> or call (301) 263-9000.

✓ Applicants must meet all the following criteria:

- · ACG Member at time of application
- U.S. or Canadian-based physician (MD or DO)
- Faculty appointment as part of a gastroenterology or hepatology department at a university, medical school, or other healthcare institution at the time of application or practicing gastroenterologist or hepatologist in a community practice
- Pilot Data Required (if not available, choose a different grant category: Pilot)

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★ The following are not eligible for this award:

- Fellows-in-training.
- Projects that support laboratory or animal research projects.
- ACG will not grant more than two Clinical Research Awards in any category to former or current Principal Investigators on R01, P01, U01, VA Merit Awards, or Hughes grants
- Award overlap: ACG does not provide duplicate funding including other diversity -focused grants [If part of a larger study, must explain how funds are not duplicated].
- Applications utilizing the same science may not be submitted for two different ACG grant categories (for example
 the same project/science is submitted for the Health Equity Research Award and Clinical Research Award) and if
 this occurs they will not be evaluated by the Committee.
- ACG limits funding for a PI to one grant in a single award cycle. If a given investigator submits projects in two or more RFA categories and more than one is deemed worthy of funding, the larger grant will be funded.
- If the applicant was awarded an ACG research award within the last three (3) years, they cannot apply for the same grant category in which they were awarded. They may apply for a different grant category, as the College is not trying to limit progression of research (pilot award to CRA or JR Faculty Award), but rather the same investigators being funded repeatedly.

■ A complete application consists of two separate components:



- A single Adobe PDF document comprising (but not limited to) the following: application checklist (include the list located at the end of this document as the first page of the submitted PDF), research proposal (limited to 5 pages), budget, biosketches for the Principal Investigator and others involved in the proposed research, other funding support details, IRB forms, COI statement (if applicable), and any letters of support from collaborators.
- 2. Completion of required tasks via the online grant system: upload the completed research proposal PDF which includes the application checklist; confirm ACG membership; provide full contact information for all Investigators submit a 350-word abstract of the proposed research; indicate IRB approval status; list all Investigators and any potential conflicts of interest. See "Submitting the Application" below for instructions and requirements.

- Required elements for the full research proposal document (i.e., the PDF that will be uploaded to the online grant system):
 - A. FORMATTING—Format all pages with ½" margins and use a font no smaller than 11 point. All pages must include a page number in the left header. All pages must include the PI name and grant type in the right header, in the following format:

Last name, First name Award Type

- **B.** CHECKLIST—Include the Application Checklist listed at the end of this document, as the first page of the PDF uploaded to the grant system.
- C. RE-SUBMISSIONS—The Committee requires applicants who have applied previously to provide additional information and resubmit the application. For re-submissions, in addition to selecting "Yes" in the resubmission field of the online system, you must provide a cover letter responding to the reviewer's critiques/outlining how you have updated your application. This should be included as the first section of your Research Proposal, as part of the PDF upload to the grant system. Limit to 2 pages.
- D. GLOSSARY OF TERMS (optional)—Include if multiple terms are defined throughout the proposal. This document is included before the Research Proposal, after the checklist and the re-submission cover letter (if applicable). Limit to one page.
- **E. RESEARCH PROPOSAL**—Limit to 5 pages (excluding references). Outline the proposed research. This should include the following sections:
 - Specific Aims—Provide a clear description of the study objectives. Consider the following questions:
 - What is the hypothesis to be addressed? What are the immediate objectives? What are the ultimate objectives? How does the proposed research fit into an overall research program?
 - Background/Significance—State how the proposed work bears on prior work and indicate how it will extend
 the boundaries of current knowledge.
 - Pilot Data/Previous Work—Provide a summary of pilot data/previous work.
 - Research Plan—Provide a detailed research plan, including the inclusion/exclusion criteria for enrollment, detailed
 methods, the data that are to be collected, and how data will be analyzed. Provide detailed sample size estimates.
 Grants without a statistical analysis section or sample size justification are unlikely to be successful.
- F. DESCRIPTION OF HEALTH EQUITY IMPACT—This REQUIRED section should be limited to 1 page. The Robert Wood Johnson Foundation defines Health Equity as "For the purposes of measurement, health equity means reducing and ultimately eliminating disparities in health and its determinants that adversely affect excluded or marginalized groups." Describe how completing the proposed project would move the needle towards achieving health equity. Describe how the proposal will collect or utilize social determinants of health. Clearly indicate which barriers to health equity this project will attempt to impact. How will this project engage patients and/or community partners? Examples may include 1) presenting the study design to a community advisory board or groups for input and feedback, 2) seeking advice on how to recruit and engage patients from different communities, or 3) joint planning with community partners on how to disseminate culturally appropriate findings or other relevant health information. Some of the funding may be used to support community engagement if adequately justified (see the budget section for additional details). It is recommended that applicants contextualize levels and domains of influence that lead to disparities in health outcomes—refer to the National Institute on Minority Health and Health Disparities Research Framework.
- **G. DESCRIPTION OF RESEARCH ENVIRONMENT**—Limit to 1 page. Describe the research environment, resources, and how this environment will provide enhanced support for the proposal. This section should describe how the research environment contributes to the success of the project and what type of institutional support, available equipment, and other additional resources will be accessible to the investigators. Additionally, elaborate as to how this specific environment is conducive to the project in terms of access to patients, samples, knowledge, or any collaborative arrangements (e.g., additional skills or referrals provided by collaborators). This section should help the reviewers understand the feasibility of completing this project.
- H. REFERENCES—Include a separate section for references. Be judicious in the use of references.
- I. BUDGET AND JUSTIFICATION—Include a separate section for the budget and justification. Use the required <u>ACG budget format</u>. The budget should indicate all expenses for each year of the award. The budget justification should be listed on a separate page, after the budget template, with an explanation for each budget item (for example: justification for the number of hours supported by the grant, how statistical support will be utilized, etc.). Funding for this award will provide support of up to \$75,000 for research costs (50k year-one, 25k year-two, based on progress).

Allowable costs:

- Salary support for other personnel (biostatistician, computer programmer, research coordinator, research nurse, etc.) if adequately justified.
- Labs, supplies, and equipment.
- Funds for community engagement (focus group, expertise) may be included if adequately justified.

Costs <u>not</u> supported:

- Salary support for Principal Investigator or Co-Investigators.
- Major equipment acquisition
- Manuscript preparation
- Travel
- Indirect costs (i.e., university overhead)





- J. INSTITUTIONAL REVIEW BOARD (IRB) STATUS—Include the IRB approval letter or indicate if IRB approval is pending. If IRB approval is pending at the time of submission and the grant proposal is subsequently approved for funding, funds will not be released until the IRB approval letter is received by the ACG. If the proposal is requesting funds for reimbursement of human subjects or where the project studies care outside of standard of care a copy of the IRB-approved consent form is required prior to funding as well.
- K. CONFLICT OF INTEREST STATEMENT—Include, if applicable.
- L. BIOSKETCHES—Provide these for the Principal Investigator, Co-Investigators, and anyone critical to the completion of the project. Use the NIH format and adhere to the NIH 5-page limit. (For sample format see the NIH webpage at grants.nih.gov/grants/forms/biosketch.htm.)
- M. OTHER RESEARCH SUPPORT—List this information on separate pages. List the title, funding agency, total direct costs, dates, including expected dates of notification of pending applications for all current and pending funding for Principal Investigator, and Co-Investigators. (Use NIH format: grants.nih.gov/grants/forms/othersupport.htm.)
- N. LETTERS OF SUPPORT—While not required, we HIGHLY encourage including Letters of Support to demonstrate the other investigators' involvement and support of the project (example: other research sites providing patients, specialists who will provide specialized expertise or support from the institution for the project). This can also include a letter from a mentor or other collaborators involved in the health equity field.
- O. APPENDICES—May be included (if needed) for data collection forms. Do not use to expand Research Proposal.
- ☐ All applications must be submitted online. The online grant application site will open September 5, 2023; a link to the site will be available at gi.org/research-awards. The submission deadline is Monday, December 4, 2023, at 11:59 pm Eastern Time. This deadline will be strictly enforced, and no exceptions will be made.

Once you begin the online application process, you will be able to save your work and return to complete it until the submission deadline. As part of the online application process, applicants are required to provide information about others, such as institutional addresses and potential conflicts of interest for Co-Investigators, the Responsible Investigator, etc. We encourage applicants to gather all the necessary information early and not wait until the last minute.

The following tasks must be completed via the online grant system to successfully submit an application for grant consideration:

- A. INDICATE PROPOSAL TITLE AND SELECT GRANT TYPE—The title should be concise and reflect the proposed research. Select the "Health Equity Research Award" grant type. (Please note, the same project should not be submitted for multiple ACG grant types, and will not be considered if this occurs, i.e., do not submit the same proposal for the Clinical Research Award and the Junior Faculty Development Award.)
- **B. ACG MEMBERSHIP VERIFICATION**—You must provide an ACG member ID for one of your investigators. To look up your member ID number, log into gi.org/membership then click "My ACG" from the menu on the top right. Member ID is listed below Date of Birth.
- C. ADD INVESTIGATORS—List the PI and, Co-Investigators. Enter their names, ACG member status (and year joined if available), titles, email address, role (PI, Co-Investigator), and institution names and addresses.
- D. ACKNOWLEDGEMENT OF PRINCIPAL INVESTIGATOR—Indicate agreement to abide by the grant requirements, if awarded grant funding.
- **E. INVESTIGATOR ADDITIONAL INFORMATION**—Provide the Principal Investigator's position, and state whether the Principal Investigator has an R01, P01, U01, VA Merit Award, or Hughes grant.
- **F. RESEARCH PROPOSAL ABSTRACT**—Provide an abstract of no more than 350 words that summarizes the proposed research.
- G. IRB STATUS—Verify current IRB status.
- **H. RESEARCH GRANT PROPOSAL PDF UPLOAD**—Format the file as required in the "Preparing the Research Proposal" section, including all required elements, and upload the file as directed. The file name should include the principal investigator's first and last name.
- I. CONFLICT OF INTEREST—A potential conflict of interest (COI) exists when research involves a device from which any Investigator(s) or a company may benefit. It also exists when research involves a pharmaceutical agent that is not FDA-approved for any indication. A conflict of interest exists if any Investigator holds or has submitted a patent on a device or pharmaceutical agent or is a major shareholder in a company involved in the research. If applicable, select "Yes" and include a detailed explanation within the grant system, including the names of each investigator and their potential COIs.





• Immediately following the application submission period, all applications are reviewed and scored by the ACG Research Committee, following its standardized process. Each application is reviewed by 3 reviewers who will present the grant at the Research Committee Grant Review meeting.

Reviewers consider the following when scoring applications: feasibility, the scientific and clinical significance of the research proposal, as well as methods. In evaluating the merits of an application, the Committee will consider the following:

- Scientific, Clinical, and Health Equity Significance (25%)
- Feasibility (including the availability of adequate resources, personnel, and facilities) (25%)
- Methods (50%)
 - Availability of preliminary data (12.5%)
 - Study design (25%)
 - Power, sample size, and statistical analysis (12.5%)

An applicant may submit multiple applications if these applications each utilize different science and are submitted to different grant categories. Each applicant may only receive funding for a single submission each grant cycle. If more than one project is deemed worthy of funding, the larger grant will be funded.



NOTIFICATION

AND GRANT

REQUIREMENTS

A Notification of Awards will be completed by April 1, 2024. Please do not contact ACG prior to this date to inquire about the status of your application.

- Funding: Awards consist of a total of \$75,000 (50k year-one and 25k year-two, based on progress). Funds are to be used for related expenses of the proposed research, including supplies and equipment. Funds are not to be used for: salary, major equipment acquisition; travel and manuscript preparation; or indirect costs (i.e., university overhead).
- Required Progress Reports: Awardees must file a progress report and financial report for year-one by June 30, 2024. Submit both reports to: research@gi.org. A final progress report will be submitted online through the ACG website gi.org/reporting-form-for-past-acg-grant-recipients, and financial statements will be emailed to research@gi.org.
- Abstract Presentation at an ACG Annual Scientific Meeting: ACG encourages the selected awardee to submit
 any abstracts to the ACG Annual Scientific Meeting for presentation (see ACG abstract submission details for
 requirements). If an abstract related to your research project is selected, you may submit up to \$500 in travel
 expenses (airfare/hotel) for reimbursement.
- Publication: All publications arising from work funded by this award must acknowledge support of an ACG Clinical Research Award.
- Award overlap: ACG does not provide duplicate funding.



For any questions about grant requirements, please refer to the FAQs.

Prior grant application submitters must create a new login for the grant system each year, even if you have applied for an ACG grant previously.

Technical support questions about the online submission system: Contact CadmiumCD Technical Support using the **Technical Support link on the upper right corner** of the submission site's screen, via email at Support@cadmiumcd.com or via phone at (877) 426-6323.

For any questions not answered in the RFA or <u>FAQs</u>, or reporting questions, contact us via email at <u>research@gi.org</u>.



September 5, 2023	Application submission period opens
September 15, 2023	ACG Membership application deadline (only for applications who are not ACG members or who are not in good standing—see the Eligibility Section for further details)
Monday, December 4, 2023	Application submission period closes (11:59 pm Eastern time)
By/before April 1, 2024	Award notifications are sent
July 1, 2024	Award period begins / disbursement check provided
June 30, 2024	Progress report and financial report due, if requesting year-two funding.
July 1, 2024	Year-two begins, for eligible awardees.
December 31, 2025	Final report and financial statement are due

✓ APPLICATION CHECKLIST: Health Equity Research Award

All grant applications must include this completed and signed Application Checklist as the first page of the research proposal PDF that is uploaded to the grant system. Submissions received without a signed and completed Application Checklist will be considered incomplete and will be disqualified. Check each box to indicate completeness or check the box marked N/A for items not applicable for your submission. All boxes on the checklist must be reviewed and marked accordingly. Please sign this document before submitting.

❷	Eligibility - double check full criteria, listed in eligibility section,
	prior to applying

You are a current ACG member. Confirm you are an ACG member in good standing prior to applying and you must have an ACG member number. Please note that this is different than applying for membership—all new member applications must be submitted by September 15, 2023

Your ACG Member ID is _

You are an MD or DO based in the United States or Canada. You hold a faculty appointment as part of a gastroenterology or hepatology department at a university, medical school, or health care institution at the time of application or are a practicing gastroenterologist or hepatologist at a community practice. Your research project is a clinical, translational, social science, or health services research study that aims to accelerate the clinical knowledge in managing the unique GI and hepatology healthcare concerns of underrepresented racial/ethnic minorities, women, LGBTQ+ populations, and/or those living with a disability (not derivative of gastrointestinal disease).

You are NOT a fellow-in-training.

Your submission does NOT involve animal research.

The science for this award is NOT submitted for another ACG award

There will NOT be award overlap: ACG does not provide duplicate funding (if part of a larger study, the budget explains how funds are not duplicated).

⊘ Completion

You have created an account in the ACG grant system (gi.org/research-awards)

You have a complete combined PDF, containing all necessary elements in the correct order, with this signed Application Checklist as the first page of the PDF to be uploaded to the grant system. You have completed all necessary and relevant tasks required as part of the online grant system for this award application, including investigator information (ACG member number, title, email, role for project, institution, and address of institution); a 350-word abstract of the proposed research; listing research topics; a list of any potential conflicts of interest for investigators; indication of IRB approval status; re-submission status

All pages must use 11-point font with minimum ½" margins. The upper right header of each page must include your name and the award type, in the following format:

Last name, First Name

Award Type

The upper left header of each page must include the page number. The sections of the PDF are numbered to match the Required Order of Submission as indicated on the checklist, with bold headers for each required section, and the section starts on its own page.

- 1. Application Checklist—This checklist is complete, signed by the PI, and included as the first page of the submitted PDF.
- □ □ 2. Resubmission Response Letter—If you are resubmitting this grant proposal, a 2-page (maximum) letter is included that responds to the reviewer's critiques and outlines how you have updated the application. Do not include this item if not applicable.
- ☐ ☐ 3. Glossary of Terms (Optional)—The use of abbreviations and acronyms N/A has been eliminated or minimized. A glossary of terms, if needed, has been added to assist reviewers and strengthen the submission.
 - **4. Research Proposal**—Your research proposal project description should be a maximum of 5 pages (excluding references). It should include the following sections at a minimum: Specific Aims, Background/Significance, Pilot Data/Previous Work, and Research Plan
 - 5. Description of Health Equity Impact—You are required to include up to 1 page describing the impact of the project on health equity.
 - 6. Description of Research Environment—describe the research environment, resources, equipment, and support and access to patients, samples, referrals, knowledge, or any collaborative arrangements which will support successful completion of this project. Limit to 1 page.
 - 7. References—Include a list of all necessary and relevant references as well as include citations in the project description.
 - 8. Budget and Justification—Use the required budget template and include a separate budget justification after the budget table. The budget justification should include an explanation for each budget item, including facility fees if funds are requested for this purpose. By submitting the budget, you verify there will be adequate resources to complete the project.
 - 9. IRB Status—An IRB approval letter or indication that IRB approval is pending is included. Informed consent documents must be provided where appropriate, such as projects where patient costs are reimbursed or if studying an intervention that is not part of routine care.If selected to receive the award, funds will not be released until ACG receives a copy of IRB approval.
 - 10. Conflict of Interest Statement—Include a COI statement or indicate that none exist.
 - 11. Biosketches—A biosketch for each investigator (Primary Investigator, Co-investigators) is included, all in the NIH format, maximum of 5 pages each. (grants.nih.gov/grants/forms/biosketch.htm).
 - 12. Other Research Support—List the title, funding agency, total direct costs, dates, including expected dates of notification of pending applications for all current and pending funding for Primary Investigator, Co-Investigators. (Use NIH format: grants.nih.gov/ grants/forms/othersupport.htm.)
 - ☐ 13. Letters of Support—Include any letters of support that demonstrate involvement and support from additional investigators (for example: other research sites providing patients; specialists who will provide specialized training).
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	☐ 14. Appendices (Optional)—use only if needed for data collect N/A forms. Do NOT use to expand project description.		
I certify that I have reviewed the Application Che-	klist and that all portions of my application	are accurate and in the required order and format.	
Signature of Principal Investigator	 Date		
Name (Printed)			