



ACG CLINICAL RESEARCH AWARDS

2023 CLINICAL RESEARCH PILOT AWARDS Request for Applications

This is a one-year pilot award for fellows-in-training, faculty, or international physicians to gather pilot data on a patient-oriented clinical research project in gastroenterology or hepatology.

 **DEADLINE: MONDAY, DECEMBER 5, 2022 AT 11:59 PM EDT**

 **APPLY: gi.org/research-awards**

 **Award Amount: \$15,000** (one-year award)

 **Award period/length of award: July 1, 2023 - June 30, 2024**

The ACG Institute for Clinical Research and Education and the American College of Gastroenterology (ACG) are proud to support pilot projects of up to \$15,000 to encourage clinical research among trainees and junior faculty, to be funded from July 1, 2022 - June 30, 2023. Pilot awards do not require previous work or preliminary data, and do not cover randomized controlled trials.

All applications must be submitted online. The grant site will open to submissions in early September 2022, and close on Monday, December 5, 2022, at 11:59pm (Eastern time).

The goal of the **Clinical Research Pilot Award** is to assist promising clinical researchers in developing research careers that have a direct bearing on clinical gastrointestinal practice.

This grant is designed to support 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, including any translational, clinical, social science, or health services research studies that pertain to managing such patients or conditions. For example, a study about microbiota would be appropriate, if it pertains to a digestive disease. In contrast, a study that is principally about HIV would likely not be appropriate unless it directly relates to how HIV affects digestive health. (For questions on study relevancy, contact the grant administrator at research@gi.org.) Since its inception in 1994, the ACG Institute has provided over \$27 Million in funding for Clinical Research Awards to over 699 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 Institute's annual fundraising campaign – The G.U.T. Fund.



ELIGIBILITY

✓ **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, 2022. To Join ACG, [click here](#). For questions on ACG membership, please email membership@gi.org or call (301) 263-9000.

✓ **Applicants must meet all the following criteria:**

- ACG Member at time of application
- U.S., Canadian, and International Members eligible
- Physician, PhD, or equivalent (e.g., MD, DO, MBBS, PhD)
- Physicians in training (fellows) are eligible to apply provided that the work is conducted under the supervision of a Responsible Investigator, who is a more senior or experienced investigator at the faculty level, who is also part of a gastroenterology or hepatology department
- No Pilot Data Required (if pilot data is available, choose a different grant category: Clinical Research Award)

✗ **The following are not eligible for this award:**

- ACG will not grant more than two Clinical Research Awards to former or current Principal Investigators on R01, P01, U01, VA Merit Awards or Hughes grants
- Projects that support laboratory or animal research projects, unless the work cannot be done in humans.
- Those who hold the position of full professor at an academic institution.
- Award overlap: ACG does not provide duplicate funding [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 both the Junior Faculty Award and Clinical Research Award) and if this occurs they will not be evaluated by the Committee.



PREPARING THE RESEARCH PROPOSAL

📄 **A complete application consists of two separate components:**

1. 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 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 Responsible Investigator, or collaborators.
2. Completion of required tasks via the online grant system: upload the completed research proposal PDF, which includes the application checklist; provide confirmation of 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.



PREPARING THE RESEARCH PROPOSAL (Cont.)

-  **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. Eliminate or minimize the use of abbreviations and acronyms. Provide a glossary of terms if needed to assist reviewers and strengthen your submission. 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 when resubmitting the application. For re-submissions, in addition to selecting “Yes” in the re-submission 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. 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.
 - **Future Directions**—Describe how the researchers intend to use the pilot data. Will this lay the groundwork for future study? Will it help the researchers learn a new skill which can be applied to further research? Will it have any clinical applicability or build on the current knowledge? How does it extend the boundaries of current knowledge, or might it lead to changes in clinical practice?
 - **Pilot Data/Previous Work**—Pilot awards of ≤\$15,000 do not require previous work or preliminary data. Be sure to select the appropriate grant type in the online application system (from the pull-down menu, specify “Clinical Research ‘Pilot Study’ Award ≤\$15,000” for pilot grants).
 - **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. Research plans without a statistical analysis section or sample size justification are unlikely to be successful.
- E. 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.
- F. REFERENCES**—Include a separate section for references. Be judicious in the use of references.
- G. BUDGET AND JUSTIFICATION**—Include a separate section for the budget and justification. Use the [ACG budget format](#). The budget should indicate all expenses for the grant period. 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 \$15,000 for research costs.
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| <i>Allowable costs:</i> <ul style="list-style-type: none">• Salary support for other personnel (biostatistician, computer programmer, research coordinator, research nurse, etc.) if adequately justified.• Labs, supplies, and equipment. | <i>Costs <u>not</u> supported:</i> <ul style="list-style-type: none">• Salary support for Principal Investigator or Co-Investigators.• Major equipment acquisition | <ul style="list-style-type: none">• Manuscript preparation• Travel• Indirect costs (i.e., university overhead) |
|---|---|--|
- H. 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.
- I. CONFLICT OF INTEREST STATEMENT**—Include, if applicable.
- J. BIOSKETCHES**—Provide these for the Principal Investigator, Responsible Investigator (required if PI is a fellow-in-training), and anyone critical to 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)



PREPARING THE RESEARCH PROPOSAL (Cont.)

- K. 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, Responsible Investigator, and Co-Investigators. (Use NIH format: grants.nih.gov/grants/forms/othersupport.htm)
- L. LETTERS OF SUPPORT**—These may be included 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 institution for project). If you are a fellow-in-training, include a letter of support from your Responsible Investigator..
- M. 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 in early September; a link to the site will be available at gi.org/research-awards. The submission **deadline is Monday, December 5, 2022, 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 clearly reflect the proposed research. Select the “Clinical Research Pilot Award <\$15,000” 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 Pilot Award and for the Clinical Research 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 Principal Investigator, Co-Investigators, and Responsible Investigator (if you are a fellow-in-training). Enter their names, ACG member status (and year joined if available), titles, email address, role (Principal Investigator, Co-Investigators, and Responsible Investigator, and institution names and addresses.
- D. ACKNOWLEDGEMENT OF PRINCIPAL INVESTIGATOR**—Indicate agreement to abide by the grant requirements, if awarded grant funding. This must be signed by the Responsible Investigator if the Principal Investigator is a fellow-in-training. The grant system will prompt you to select a Responsible Investigator, who will receive an email to complete this form.
- E. INVESTIGATOR ADDITIONAL INFORMATION**—Provide PI's position. Also state whether the PI is a Trainee. Add the Responsible Investigator name, email, 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. RE-SUBMISSIONS**—For re-submissions, select “Yes” in the re-submission field of the online system.
- H. IRB STATUS**—Verify current IRB status.
- I. 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.
- J. 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.



SUBMITTING THE APPLICATION



APPLICATION REVIEW PROCESS

👁️ **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, 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 and clinical significance (25%)
- Feasibility (including availability of adequate resources, personnel, and facilities) (25%)
- Methods (50%)
 - Future directions (12.5%)
 - Study design (25%)
 - Power, sample size and statistical analysis (12.5%)
 - The same project should not be submitted for multiple grant types and will not be considered if this occurs.

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 submission from a single applicant is selected for funding, the Research Committee will determine which of the projects to fund.



AWARD NOTIFICATION AND GRANT REQUIREMENTS

🔔 **Notification of Awards will be completed by April 1, 2023** Please do not contact ACG prior to this date to inquire about the status of your application.

- **Funding:** Awards consist of a total of up to \$15,000. 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).
- **A. Required Progress Reports:** Awardees must file a final progress report that includes a financial statement by December 31, 2024, on completion of the project. Progress reports 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.



QUESTIONS OR ASSISTANCE

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 [FAQs](#), or reporting questions, contact us via email at research@gi.org.



IMPORTANT DATES

September, 2022	Application submission period opens
September 16, 2022	ACG Membership application deadline (only for applications who are not ACG members— see the Eligibility Section for further details)
Monday, December 5, 2022	Application submission period closes (11:59 pm Eastern time)
By/before April 1, 2023	Award notifications are sent
July 1, 2023	Award period begins / disbursement check provided
December 31, 2024	Final report and financial statement due

✓ APPLICATION CHECKLIST: Clinical Research Pilot 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.**

☑ 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 16, 2022.
- Your ACG Member ID is _____.
- You are a physician, PhD, or equivalent (e.g., MD, DO, MBBS, PhD) based in the United States, Canada, or internationally.
- If you are a physician in training (fellows), a Responsible Investigator, ^{N/A} a more senior or experienced investigator at the faculty level in the department of gastroenterology or hepatology, is included in your application, and will provide supervision for this project.
- NO pilot data is associated with the research project (If you have pilot data consider applying for the Clinical Research Award category).
- Your project involves patient-oriented clinical research in the field of gastroenterology or hepatology.
- Your submission does NOT involve animal research, unless the work cannot be done in humans.
- You are NOT a former or current recipient of an R01, P01, U01, VA Merit Awards or Hughes grants (ACG limits the number of ACG research awards given to recipients of these award types).
- The science for this award is NOT submitted for another ACG award category.
- There will NOT be award overlap: ACG does not provide duplicate funding (if part of a larger study, explain 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.

☑ Format of Submitted PDF

- All pages must use 11-point font with minimum ½” margins.
- The use of abbreviations and acronyms has been eliminated or minimized. A glossary of terms, if needed, has been added to assist reviewers and strengthen the submission.
- 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 each bolded header section starts on its own page.

☑ Required Order of Submission

- 1. Application Checklist**—This checklist is complete, signed by the Principal Investigator, 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. ^{N/A}
- 3. 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, Future Directions, and Research Plan.
- 4. 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.
- 5. References**—Include a list of all necessary and relevant references as well as citations in the project description.
- 6. Budget and Justification**—Use the [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.
- 7. 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.
- 8. Conflict of Interest Statement**—Includes a COI statement or indicates that none exist.
- 9. Biosketches**—A biosketch for each investigator (Principal Investigator, Responsible Investigator [if a fellow-in-training], any other investigators involved) is included, all in the NIH format, maximum of 5 pages each. (grants.nih.gov/grants/forms/biosketch.htm).
- 10. 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 Principal Investigator, Responsible Investigator (if relevant), and other investigators involved. (Use NIH format: grants.nih.gov/grants/forms/othersupport.htm)
- 11. Responsible Investigator Letter**—A single page letter from the Responsible Investigator (only necessary if you are a fellow-in-training) confirms that you have adequate support and time to complete the project. ^{N/A}
- 12. Other Letters of Support** (Optional)—Included any optional letters of support that demonstrate involvement and support from additional investigators (for example: other research sites providing patients; specialists who will provide specialized training). ^{N/A}
- 13. Appendices** (Optional)—Attach data collection forms. This section does not expand the research proposal. ^{N/A}

I certify that I have reviewed the Application Checklist and that all portions of my application are accurate and in the required order and format.

Signature of Principal Investigator

Date

Name (Printed)