



ACG CLINICAL RESEARCH AWARDS

2021 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: FRIDAY, DECEMBER 4, 2020 AT 11:59 PM EDT**

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

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

 **Award period/length of award: July 1, 2021–June 30, 2022**

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, 2021 – June 30, 2022. Pilot awards do not require previous work or preliminary data, and do not cover randomized controlled trials. The number and size of awards will be determined by the ACG Research Committee.

All applications must be submitted online. The grant site will open to submissions in early September 2020, and close on Friday, December 4, 2020, 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 \$22 Million in funding for Clinical Research Awards to over 660 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 While research that explores mechanisms of human disease is highly encouraged, the research projects should be translational in nature; i.e., have 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 G.U.T. Fund.



ELIGIBILITY

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

- ACG Member* (one person on the team must be a member)
- U.S., Canadian, and International Members eligible
- Physician (MD, DO, or PhD)
- Physicians in training (fellows) are eligible to apply provided that the work is conducted under the supervision of a Responsible Investigator, a more senior or experienced investigator at the faculty level
- No Pilot Data Required (if pilot data is available, choose a different grant category: Clinical Research Award)

✗ **The following are not eligible to 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.
- Award overlap: ACG does not provide duplicate funding [If part of larger study, must explain how funds are not duplicated].
- Those who hold the position of full professor at an academic institution.

****Important!** Please note that at least one person on your Team must be an ACG member to apply for this grant. All member applications must be submitted by September 25, 2020 in order to be eligible for review at the October Credentials Committee meeting, which is the last opportunity to be approved for full membership prior to the grant application deadline. To Join ACG, [click here](#). For questions on ACG membership, please email membership@gi.org or call 301-263-9000.*



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: 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; 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. 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. 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.
- C. 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.
- D. REFERENCES**—Include a separate section for references. Be judicious in the use of references.
- E. BUDGET AND JUSTIFICATION**—Include a separate section for the budget and justification. The budget should be listed as a table, indicating all expenses for the grant period. The budget justification should be listed after the budget table, with an explanation for each budget item. Funding for this award will provide support of up to \$15,000 for research costs - salary support for other personnel (biostatistician or administrative coordinator) if adequately justified, and support for supplies and equipment. Costs not supported: major equipment acquisition; travel and manuscript preparation; indirect costs (i.e., university overhead); and salary support for principal investigators and co-investigators.
- F. 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, a copy of the IRB-approved consent form is required prior to funding as well.
- G. CONFLICT OF INTEREST STATEMENT**—Include, if applicable.
- H. 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.)
- I. 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.)
- J. 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.
- K. APPENDICES**—May be included (if needed) for data collection forms. Do not use to expand Research Proposal.



SUBMITTING THE APPLICATION

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/acg-institute/research-awards. The submission **deadline is Friday, December 4, 2020 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 to not wait until the last minute.

The following tasks must be completed via the online grant system in order 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 Contact Information” from the menu on the left. Member ID is listed below Date of Birth.
- C. ADD INVESTIGATORS**—List the PI, 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 (PI, Co-Investigator, 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 PI 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’s 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 names of each investigator and their potential COIs.



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 on 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 (25%)
 - Study design (50%)
 - Power, sample size and statistical analysis (25%)
 - The same project should not be submitted for multiple grant types and will not be considered if this occurs.

If an individual submits more than one grant proposal, only one award can be made for a given Principal Investigator. If a given investigator submits both a pilot and a larger clinical research grant deemed worthy of funding, the larger grant will be funded.



AWARD NOTIFICATION AND GRANT REQUIREMENTS

Notification of Awards will be completed by April 1, 2021. 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).
- **Required Progress Reports:** Awardees must file a final progress report that includes a financial statement by December 31, 2022, 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 Help@ConferenceAbstracts.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, 2020	Application submission period opens
September 25, 2020	ACG Membership application deadline (only for applications who are not ACG members—see the Eligibility Section for further details)
Friday, December 4, 2020	Application submission period closes (11:59 pm Eastern time)
By/before April 1, 2021	Award notifications are sent
July 1, 2021	Award period begins / disbursement check provided
December 31, 2022	Final report and financial statement due

✓ APPLICATION CHECKLIST:

☑ Do you meet all of the following eligibility criteria (full criteria listed in eligibility section)?

- You are a U.S., Canadian or International physician.
- You are a MD, DO, or PhD.
- You have a responsible investigator who will provide supervision for this project, if you are a fellow-in-training.
- Your project involves patient-oriented clinical research in the field of gastroenterology or hepatology. Your project does not involve animals (this type of research is not eligible).

☑ Is a member of your team a current ACG Member? Confirm that they are an ACG member in good standing prior to applying—this is different than applying for membership—they must have an ACG member number (see instructions in eligibility section).

☑ Have you created an account in the grant system, and is your application formatted as required (see requirements in formatting section above)?

- You have created an account in the ACG grant system (www.gi.org/acg-institute/research-awards).
- Application is formatted to include: ½" margin, headers with name, award type, and page numbers.

☑ Have you provided the following required information in the grant system?

- | | |
|--|---|
| <input type="checkbox"/> Investigator information (membership ID, title, email, role for project, institution, address of institution) | <input type="checkbox"/> Abstract |
| | <input type="checkbox"/> Topic categories |
| | <input type="checkbox"/> COI |
| | <input type="checkbox"/> IRB status |
| | <input type="checkbox"/> Re-submission status |

☑ Have you prepared all of the following Research Proposal components, and compiled them into a single PDF document, in the following order?

- If yours is a re-submission, double-check that you have responded to the reviewer's critiques, and that you have updated your proposal with any suggested changes.
- Project Description—The project description includes all the sections outlined above, adheres to the 5-page limit, and all tables and figures are labeled. If pilot data is available, consider applying to the Clinical Research Award grant type.
- References—These are listed where applicable and citations are included in the project description.
- Budget & Justification—A budget table is included with a clear justification of costs. Costs covered by the institution vs. covered by the ACG Clinical Research Pilot Award are clearly indicated. Any other costs needed for the project are clearly explained. By submitting the budget, you are verifying that there will be adequate resources to complete the project.
- The COI statement included, if applicable.
- Confirmation of IRB approval is included, if available
- Biosketches—A biosketch for each investigator is included, and all are in the NIH format.
- Information about other grant support, if applicable, is included.
- Letters of Support—Letter of support is included from your responsible investigator (if you are a fellow-in-training). Letters of support for any co-investigator or other relationship, where other expertise or referrals are needed to complete the project, are included.

☑ Are the PDF Components in the correct order and have you uploaded the complete PDF of your Research Proposal to the grant submission site?