2022 ESTABLISHED INVESTIGATOR BRIDGE FUNDING AWARD

Request for Applications

This is a two-year award supporting 50% protected time as bridge funding for established investigators.

📅 DEADLINE: FRIDAY, DECEMBER 3, 2021 AT 11:59 PM EDT
NOTE: Pre-Qualification Application Due November 1, 2021. To Submit: bit.ly/33guW6k

➡️ APPLY: gi.org/research-awards

🏆 Award Amount: $300,000 / 2-YEAR AWARD ($150K PER YEAR)
📝 Award period/length of award: July 1, 2022 - June 30, 2024

The ACG Institute for Clinical Research and Education and the American College of Gastroenterology (ACG) are proud to support established clinical gastroenterology or hepatology researchers, who have experienced a lapse in federal program funding which requires bridge support to sustain their robust research programs, and invite eligible applicants to apply for a $300,000, two-year bridge funding award, to be funded from July 1, 2022 - June 30, 2024. This award provides short-term bridge funding to sustain an investigator’s independent research program between federal grants and is only available to ACG members.

All applications must be submitted online. The grant site will open to submissions in early September 2021, and close on Friday, December 3, 2021, at 11:59pm (Eastern time).

The goal of the Established Investigator Bridge Funding Award is to provide short-term (up to two-year) funding to established clinical scientists with a proven track record of federal program (non career-development) funding in innovative and impactful clinical research in gastroenterology or hepatology. With the paucity of federal agencies willing to fund GI and hepatology clinical research and federal funding levels at less than 15%, intermittent gaps in federal funding are a reality in the research career of an independent clinical investigator. This bridge funding grant is designed to support researchers principally focused on digestive or liver diseases, and to sustain their competitive, patient-oriented research programs during such a gap in federal program funding.

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 for Clinical Research and Education has provided over $24 Million in funding to over 676 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 G.U.T. Fund.

ELIGIBILITY

✔ Applicants must meet all the following criteria:
  • ACG Member* (Required at time of application)
  • U.S. or Canadian-based physician (MD or DO)
  • Established Investigator definition:
    • At least 8 years out of fellowship or terminal training program at time of application
    • Evidence of successful federal funding beyond the level of a career development award.
    • Faculty appointment (60% or more academic appointment) as part of the gastroenterology or hepatology department at a university, medical school or other healthcare institution at time of application
    • Evidence of recently concluded federal clinical or translational research award within the last 2 years in gastroenterology or hepatology, such as NIH R01, or VA Merit Award. National Science Award, Department of Defense and CIHR multi-year project grant awards of equivalency [minimum direct costs of $400,000/year] will be considered. Career Development Awards at an institutional, provincial, or professional society (state or national) level are ineligible as qualifying awards. Additionally, applicants must demonstrate one of the following:
      1. Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to a federal agency [i.e., eRA commons routing information] or letter of intent from institutional grant awards office)
      2. Evidence of new federal application (scored but not funded research grant) to be re-submitted (provide summary sheets and scores)
  • Able to guarantee 50% protected research time for entirety of the grant period. Candidates must devote at least 50% of their effort to clinical research related to gastroenterology or hepatology. A letter from the division chief or department chair must certify that the award will provide 50% protected time to the recipient, regardless of the amount budgeted for salary, in accordance with the terms of the award.

✘ The following are not eligible for this award:
  • Individuals who have only received career development funding at an institutional, provincial, or professional society (state or national) level are not eligible.
  • Fellows-in-training.
  • Early career faculty.
  • Projects that support laboratory or animal research projects.
  • Award overlap: ACG does not provide duplicate funding. The same science may not be used in applications for two ACG grant types (ex: applying to both the Bridge Funding Award and Clinical Research Award with the same science).

*Important! Full ACG membership in good standing is required. Applicants must have an approved ACG membership no later than October 2021 (Applications are due by September 17, 2021). To Join ACG, click here. For questions on ACG membership, please email membership@gi.org or call 301-263-9000.
A complete application consists of three separate components:

1. Submission of Required Pre-Qualification Application detailing the name of the grant, specific aims, brief research plan outline, current fundings status. This should be limited to two pages and submitted to the ACG by November 1, 2021. Applicants will then be notified as to whether they should proceed with formal grant submission.

2. 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), application checklist (include the list located at the end of this document as the first page of the submitted PDF), research proposal (limited to 8 pages), budget, biosketches for candidate and other investigators involved in the proposed research, other support funding details, IRB forms, COI statement (if applicable), and letters of support.

3. 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.

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. ELIGIBILITY CONFIRMATION LETTER—Letter Confirming you are eligible to apply for this award type. You will receive this letter after you submit the Pre-Qualifying Application.

D. 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 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 beginning of your Research Proposal, after the letter confirming your eligibility, as part of the PDF upload to the grant system. Limit to 2 pages.

E. RESEARCH PROPOSAL—Limit to 8 pages (excluding references). Outline the proposed research. In general, this should be a series of linked projects developed around a common theme, and should include the following sections:

• Specific Aims—Provide a clear description of the study objectives. 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—This award type does not require pilot data. However, if the applicant has prior data pertinent to the present application, it should be briefly presented here. References to published work are preferred to detailed descriptions of published manuscripts.

• Research Plan—Provide a detailed research plan, including the inclusion/exclusion criteria for enrollment, methods to be used, the kinds of data that are to be collected, and how these data will be analyzed. Provide detailed sample size estimates. Grants without a statistical analysis section or sample size justification are unlikely to be successful.

• Current Funding Status—Indicate to which federal funding agency the initial grant application was submitted, and the outcome of this submission. Further indicate plans for re-submission. Also, address how the additional funding provided by this award will help address shortcomings in the initial research submission, as identified by the study section or review committee who assessed the initial grant.

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. The budget should be listed as a table, indicating all expenses for each year of the award, with quantity and units for each item (ex: number of hours, and rate for salary and fringes). The budget justification should be listed after the budget table, with an explanation for each budget item (ex: justification for number of hours supported by the grant, how statistical support will be utilized, etc.). Funding for this award will provide salary support for the PI and co-investigators, and salary support for other personnel (research nurse, computer programmer, statistician) if adequately justified. Expenses for supplies and equipment are allowed, and facility fees are allowed if adequately justified. Costs not supported: major equipment acquisitions; travel and manuscript preparation; indirect costs (i.e., university overhead).
Preparing The Research Proposal (cont.)

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, 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 primary investigator, co-investigator(s), 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)

K. 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.

L. 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 the Primary Investigator and Co-Investigators. (Use NIH format: grants.nih.gov/grants/forms/ othersupport.htm). The PI must include one of the following: 1) Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to federal agency) or 2) Evidence of new federal application (scored but not funded research grant) to be re-submitted. Provide summary sheets and scores.

M. INSTITUTIONAL SUPPORT—This letter from either the Division Chief or Department Chair should indicate strong commitment from the division to support the candidate by protecting time for research and for providing adequate research facilities. The letter must certify that the award will provide 50% protected time to the recipient, reserved for the proposed research, in accordance with the terms of the award, regardless of the support budgeted in the application for the recipient’s salary. Limit to 2 pages.

N. OTHER LETTERS OF SUPPORT (optional)—Provide letters from any other collaborators, such as those supplying patient referrals, if applicable. These may be included to demonstrate the other investigators’ involvement and support of the project (example: other research sites providing patients, or collaborator supplying patient referrals, if applicable. These may be included to demonstrate the other investigators’ involvement and support of the project (example: other research sites providing patients, or collaborator providing a unique set of skills required for the project).

O. APPENDICES—Use (if needed) for data collection forms. Do not use to expand project description.

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 Friday, December 3, 2021 at 11:59 pm Eastern Time. This deadline will be strictly enforced, and no exceptions will be made.

Note: Required Pre-Qualification Application due November 1, 2021.

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, 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 “Established Investigator Bridge Funding 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 a Established Investigator Bridge Funding Award and a Clinical Research Award.)

B. ACG MEMBERSHIP VERIFICATION—You must provide your ACG member ID. 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 and any 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 PI’s academic position, and state whether the principal investigator has received federal clinical or translational research in gastroenterology or hepatology (within the last two years), such as NIH R01 or VA Merit Awards, National Science Awards, DoD or CCHIR multi-year project grant awards of equivalency [min. direct costs of $400,000 /yr] will be considered. Career Development Awards at an institutional, provincial, or professional society (state or national) level are ineligible as qualifying awards.

Applicants must also demonstrate either: 1. Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to federal agency) or 2. Evidence of new federal application (scored but not funded research grant [i.e., eRA commons routing information] or letter of intent from institutional grant awards office) to be re-submitted (provide summary sheets and scores).
F. RESEARCH PROPOSAL ABSTRACT—Provide an abstract of no more than 350 words that summarizes the proposed research. In this section, you will also be asked to enter the topic area for your application.

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 candidate’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 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.

Reviewers consider the following when scoring applications: the feasibility, scientific and clinical significance of the research proposal, attributes of the candidate (previous publication and funding record) and qualifications to perform high-quality research, and strength of the institutional environment, including a letter of support for 50% protected time if the proposal is funded.

In evaluating the merits of an application, the Committee will consider two categories of criteria, each comprising 50% of the overall assessment: 1) Project Merit, and 2) Individual Merit

1. Project Merit—50% of score includes:
   • Scientific and clinical significance (25%)
   • Feasibility (including availability of adequate resources, such as personnel and facilities) (25%)
   • Methods (50%)
     • Availability of preliminary data (25%)
     • Study design (50%)
     • Power, sample size, and statistical analysis (25%)

2. Individual Merit (Credentials / Institutional Support / Previous record of funding success)—50% of score includes:
   • Applicant’s Credentials
   • Previous success in attracting and sustaining independent research funding
   • Institutional Environment (including a letter from institution’s Division Chief / Department Chair supporting 50% protected time)

In general, the proposed research should be a series of linked projects developed around a common theme. The description of a proposed project should provide enough detail to assess the scientific merit, feasibility, and analytic strategy.

**AWARD NOTIFICATION AND GRANT REQUIREMENTS**

Notification of Awards will be completed by April 1, 2022. Please do not contact ACG prior to this date to inquire about the status of your application.

• **Funding:** Awards consist of $150,000 per year for two years, for a total award of $300,000. Funds are to be used for related expenses of the proposed research, including salary, supplies, and equipment. Funds are not to be used for: major equipment acquisition; travel and manuscript preparation; indirect costs (i.e., university overhead).

• **Required Progress Reports:** Awardees must file a progress report, on completion of the first year, for review by the ACG Institute Director and Research Chair, prior to the release of year two funding. This report must include proof of ongoing application for renewal of federal funding or new federal funding. A final report is due at the completion of the funding period must include an update on notice of award for subsequent funding. A final financial statement indicating allocation of funds is required. All reports must also be submitted 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.

• **Publication:** All publications arising from work funded by this award must acknowledge ACG support in any publications that result from the research.

• **Award overlap:** ACG does not provide duplicate funding. The aim of this award is to sustain the research until federal or other funding is obtained.

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 Bridge Funding Award and for the Clinical Research Award.
<table>
<thead>
<tr>
<th>IMPORTANT DATES</th>
<th>QUESTIONS OR ASSISTANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>September, 2021</td>
<td>Application submission period opens</td>
</tr>
<tr>
<td>September 17, 2021</td>
<td>ACG Membership application deadline (only for applications who are not ACG members—see the Eligibility Section for further details)</td>
</tr>
<tr>
<td>Monday, November 1, 2021</td>
<td>Required Pre-Qualification Application due to ACG to check eligibility.</td>
</tr>
<tr>
<td>Friday, December 3, 2021</td>
<td>Application submission period closes (11:59 pm Eastern time)</td>
</tr>
<tr>
<td>By/before April 1, 2022</td>
<td>Award notifications are sent</td>
</tr>
<tr>
<td>July 1, 2022</td>
<td>Year 1 of award period begins / disbursement check provided</td>
</tr>
<tr>
<td>June 30, 2023</td>
<td>Year 1 progress report due (upon completion of first year) include any information on applications submitted for funding.</td>
</tr>
<tr>
<td>July 1, 2023</td>
<td>Year 2 of award period begins / disbursement check provided, once report approved.</td>
</tr>
<tr>
<td>June 30, 2024</td>
<td>Year 2 funding period complete</td>
</tr>
<tr>
<td>December 31, 2024</td>
<td>Final report and financial statement due (due earlier if only received one year of support)</td>
</tr>
</tbody>
</table>

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.
2022 ESTABLISHED INVESTIGATOR BRIDGE FUNDING AWARD

✓ APPLICATION CHECKLIST:

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 below AFTER verifying that the corresponding document is complete. 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 17, 2021.
☐ Your ACG Member ID is __________________________.
☐ You have completed the ACG Bridge Funding Required Pre-Qualification Application and have received a letter from ACG confirming eligibility.
☐ You are an MD or DO based in the United States or Canada.
☐ You hold a faculty appointment (60% or more academic appointment) as part of a gastroenterology or hepatology department at a university, medical school, or health care institution.
☐ You have completed fellowship more than eight years ago.
☐ You have evidence of a recently concluded federal, federal or translational research award (within 2 years) in gastroenterology or hepatology, such as an NIH RO1, VA Merit Award, National Science Award, Department of Defense and CHIR multi-year project grant awards of equivalency (minimum direct costs of $400,000/year) will be considered. NOTE: Career Development awards are not eligible.
☐ You demonstrate one of the following requirements:
☐ Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to federal agency [i.e., eRA commons routing information] or letter of intent from institutional grant awards office)
☐ Evidence of new federal application (scored but not funded research grant) to be re-submitted (provide summary sheets and scores)
☐ You will have guaranteed 50% protected clinical research time for the entirety of the award period and have a letter from the division chief that certifies 50% protected time.
☐ You are NOT a fellow-in-training.
☐ You are NOT an early career faculty
☐ You do NOT only have a Career Development Grants from a state, provincial or federal agency (these are NOT considered qualifying awards for eligibility)
☐ Your submission does NOT involve animal research.
☐ 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.

☐ 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 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.

☐ Required Order of Submission
☐ 1. Application Checklist—This checklist is complete, signed by the PI, and included as the first page of the submitted PDF.
☐ 2. Eligibility Confirmation Letter—You have completed the Pre-Qualification Application, and have included the letter of eligibility confirming you are eligible for this award type as the second page of your application.
☐ 3. 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.
☐ 4. Research Proposal—Your research proposal project description should be a maximum of 8 pages (excluding references). It should include the following sections at a minimum: Specific Aims, Background/Significance, Pilot Data/Previous Work, Research Plan, and Current Funding Status.
☐ 5. References—Include a list of all necessary and relevant references as well as citations in the project description.
☐ 6. Budget and Justification—A budget table for each year of the award with clear justification of all costs is included. Costs covered by the institution vs. the Bridge Funding Award are clearly indicated. Any other costs needed for the project are clearly explained. 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. If selected to receive the award, funds will not be released until ACG receives a copy of IRB approval.
☐ 8. Conflict of Interest Statement—Include a COI statement or indicate that none exist.
☐ 9. 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)
☐ 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 Primary Investigator, Co-investigators. (Use NIH format: grants.nih.gov/grants/forms/othersupport.htm)
☐ 11. Institutional Support—The division chief or department chair must provide a 2-page (maximum), signed letter that certifies candidate has 50% protected clinical research time and support and adequate research facilities, regardless of the support budgeted for the recipient’s salary. The letter also should indicate the requirements the institution has, with regards to applying for and receiving such funding, have been met.
☐ 12. Other Letters of Support (Optional)—Include 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).
☐ 13. Appendices (Optional)—use only if needed for data collection forms. Do NOT use to expand project description.

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)