



## THE AMERICAN COLLEGE OF GASTROENTEROLOGY REQUEST FOR APPLICATIONS 2019 CLINICAL RESEARCH AWARDS



### **Description**

The American College of Gastroenterology (ACG) is offering Clinical Research Awards of up to \$50,000 for original clinical research. For these awards, preliminary data are expected. As part of the ACG Clinical Research Award, the College also supports pilot projects of up to \$15,000 to encourage clinical research among trainees and junior faculty. Pilot awards do not require previous work or preliminary data. The number and size of awards will be determined by the ACG Research Committee.

### **Objective**

The mission of the ACG Clinical Research Awards program is to fund innovative patient-oriented research. 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, and (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, with direct applicability to clinical care. In general, studies involving animals will not be considered unless the work cannot be done in humans.

### **Eligibility**

At least one of the investigators **must be an ACG member or trainee member at the time of submission** of the grant proposal. Note that physicians in training (interns, residents, fellows) are eligible to apply provided that the work is conducted under the preceptorship of a more senior or experienced investigator. In order to assure diversity among recipients, no more than two Clinical Research Awards will be granted to former or current principal investigators on R01, P01, U01, VA Merit Awards or Hughes grants, or to those who hold the position of full professor at an academic institution. Successful applicants must agree to acknowledge ACG support in any publications that result from the research, and to submit a final report to the ACG Research Committee within 18 months of receipt of funding.

### **Selection Criteria**

In evaluating the merits of an application, the Committee will consider its scientific and clinical significance (25%), feasibility (including availability of adequate resources, such as personnel and facilities) (25%), and methods (50%). The methods component is comprised of the availability of preliminary data, if applicable (25%), the study design (50%), and power, sample size and statistical analysis (25%). 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. The same project should not be submitted for multiple grant types, and will not be considered if this occurs.

### **Review Process**

The ACG Research Committee will review the grant proposals, using its standardized process.

### **Deadline**

Submit the application through ACG's online grant application system by the **DEADLINE: Friday, December 7, 2018**. Submission instructions will be available on the College's Web site at [gi.org/grant-announcements](http://gi.org/grant-announcements) in early September. Applicants will be notified by April 1, 2019. The one-year award period will begin July 1, 2019.

### **Application Overview**

Applicants are required to submit a single Adobe PDF document comprising the complete grant submission. The single PDF document must be uploaded through the online application portal. This includes all required sections of the grant, in the order listed below. Format all pages with 1" margins and a font no smaller than 11 point. Type your name (last name, first name) and the name of the award in the upper right hand corner of each page, and the page number in the upper left hand corner of each page. **FAILURE TO ADHERE TO THESE INSTRUCTIONS WILL CAUSE THE GRANT APPLICATION TO BE RETURNED UNREVIEWED.**

### **You will be required to provide the following information through ACG's online grant system:**

1. Membership: You will be required to enter your ACG member ID number for the PI in the online application form.
2. List the Principal Investigator and all Co-Investigators, and indicate their ACG status (trainee member, member, etc). Indicate the year in which each investigator joined the ACG.
3. If a trainee is listed as the Principal Investigator, indicate the name of the Responsible Investigator. The Responsible Investigator must be a faculty member who agrees to serve as the trainee's preceptor and to be responsible for scientific and administrative oversight of the project.
4. Abstract: You will be asked to submit an abstract of no more than 350 words in the online system. Use the abstract to summarize the proposed research.

5. Institutional Review Board (IRB) status — Include the IRB approval letter in the application (see section D below). 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.
6. Conflict of interest — A potential conflict of interest exists when the research involves a device from which any investigator(s) or a company may benefit. It also exists when the 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 COI.

#### **Application Components**

**A. RE-SUBMISSIONS:** For re-submissions, in addition to selecting "Yes" in the re-submission field of the online application, you must submit a cover letter responding to the reviewers 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 2 pages.

#### **B. RESEARCH PROPOSAL — Limit proposal to 5 pages (excluding references and budget).**

- **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** — For larger grant proposals (defined as >\$15,000) pilot data/previous work is expected. Pilot awards of ≤\$15,000 do not require previous work or preliminary data. Be sure to select the appropriate grant type, from the pull down menu, in the online application system, specify "Clinical Research 'Pilot Study' Award ≤\$15,000" for pilot grants.
- **Research Plan** — Give the details of the 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.

**References** — Include a separate section for references (not included in page limit). Be judicious in the use of references.

**Budget** — Include a separate section for the budget (not included in page limit). Indicate how the funds will be allocated and **justify each budget item**, including facility fees if funds are requested for this purpose. Note that salary support for the Principal Investigator and Co-Investigators will not be provided. Salary support will be provided for other personnel (research nurse, computer programmer) if adequately justified. Support will be provided for supplies and equipment. In general, major equipment acquisitions are not supported. Travel and manuscript preparation costs are not supported. Indirect costs (i.e., university overhead) are not provided.

**C. OTHER SUPPORT:** For each investigator, list the title, funding agency, total direct costs, dates (including expected dates of notification) of all active awards and pending funding. **Use NIH format.** (To learn more see: [grants.nih.gov/grants/forms/othersupport.htm](http://grants.nih.gov/grants/forms/othersupport.htm)) Indicate whether any scientific or budgetary overlap exists, and if so, indicate how this will be addressed.

**D. IRB APPROVAL LETTER:** Include any available information (see above).

**E. CURRICULUM VITAE:** Provide for each investigator. **Use NIH format and adhere to the NIH 5-page limit.** For sample format see the NIH Web page: [grants.nih.gov/grants/forms/biosketch.htm](http://grants.nih.gov/grants/forms/biosketch.htm)

**F. SUPPORTING LETTERS:** Provide letters from collaborators, such as those supplying patient referrals, if applicable. Applications in which a physician in training serves as Principal Investigator must be accompanied by a supporting letter from the individual's program director.

**G. APPENDICES:** Use (if needed) for data collection forms. Do not use to expand Research Proposal (Section B above).

#### **Applications Must Be Submitted Electronically**

**DEADLINE: FRIDAY DECEMBER 7, 2018 | [gi.org/grant-announcements](http://gi.org/grant-announcements)**

**QUESTIONS** Phone: 301-263-9000 or email: [research@gi.org](mailto:research@gi.org)