



## THE AMERICAN COLLEGE OF GASTROENTEROLOGY 2005 CLINICAL RESEARCH AWARDS

### Description

The American College of Gastroenterology (ACG) is offering Clinical Research Awards of up to \$35,000 for original clinical research. The number and size of awards will be determined by the ACG Research Committee. In 2004, 18 Clinical Research Awards were funded for a total of \$406,498.

### Objective

The mission of the ACG Clinical Research Awards program is to fund innovative research awards that are patient-oriented. 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; i.e., have 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. Successful applicants must agree to acknowledge ACG support in any publications that result from the research, and to submit a final report within 18 months of receipt of funding.

### Board of Governors' Awards

A portion of the funds available for Clinical Research Awards is provided by the ACG Board of Governors. These awards are referred to as the Board of Governors' Clinical Research Awards. The Board of Governors' Awards are identical to the ACG Clinical Research Awards except that recipients must submit their research as abstracts to the ACG Annual Meeting or as manuscripts to the *American Journal of Gastroenterology*. If you are willing to have your grant proposal considered for a Board of Governors' Clinical Research Award, please check the appropriate box on the title page.

### 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, including 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%). In instances in which an individual submits more than one grant proposal, only one award can be made for a given Principal Investigator.

### Review Process

The ACG Research Committee will review the grant proposals.

### Deadline

An original and **12 copies** of the complete application package must be received by **NEW DEADLINE Friday December 10, 2004**. The award period will begin July 1, 2005.

### Application Instructions

ASSEMBLE THE APPLICATION MATERIALS IN THE ORDER LISTED BELOW.

#### A. Title Page

1. Use the attached form as a cover page. Type the responses.
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. State the amount of funding requested in the budget.
4. In the case in which a trainee is listed as the Principal Investigator, indicate the name of the responsible investigator. This individual agrees to serve as the trainee's preceptor and to be responsible for scientific and administrative oversight of the project.
5. Institutional Review Board (IRB) status — Include the IRB approval letter in the application (see 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 share-holder in a company involved in the research. If applicable, attach a detailed letter of explanation (see below).

**B. Abstract**

Put on a separate page immediately following the title page. Limit to 350 words. Use the abstract to summarize the proposed research.

**C. Research Grant Proposal**

Begin on a separate page immediately following the abstract. Limit to 5 pages (excluding references and budget). Use 1" margins with font size no smaller than 11 point. **ASSEMBLE THE GRANT PROPOSAL AS DIRECTED BELOW, IN THE ORDER LISTED BELOW. FAILURE TO ADHERE TO THESE INSTRUCTIONS WILL CAUSE THE GRANT APPLICATION TO BE RETURNED UNREVIEWED.**

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 — The ACG supports pilot studies. If the proposed research is a pilot study, indicate this. In general, awards for pilot studies will not exceed \$10,000. For larger grant proposals (defined as >\$10,000) pilot data/previous work is expected.

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.

References — Begin on a separate page. Be judicious in the use of references.

Budget — Begin on a separate page. 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.

**D. 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 <http://grants1.nih.gov/grants/funding/phs398/phs398.html#forms>) Indicate whether any scientific or budgetary overlap exists, and if so, indicate how this will be addressed.

**E. IRB Approval Letter:** Include (see above).

**F. Conflict of Interest Statement:** Include, if applicable (see above).

**G. Curriculum Vitae:** Provide for each investigator. Use NIH format and adhere to the NIH 4-page limit. For sample format see the NIH Web page <http://grants1.nih.gov/grants/funding/phs398/biosketch.doc>

**H. 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.

**I. Appendices:** Use (if needed) for data collection forms. Do not use to expand Section C (above).

**Applications should be sent to:**

**Research Committee, American College of Gastroenterology, 4900B South 31<sup>ST</sup> Street, Arlington, VA 22206-1656  
Telephone: 703-820-7400 (Deadline December 10, 2004)**



# ACG 2005 CLINICAL RESEARCH AWARD APPLICATION

(THIS FORM SHOULD BE USED AS THE FIRST PAGE OF YOUR APPLICATION.)

TITLE OF PROJECT: \_\_\_\_\_

## INVESTIGATORS:

Name(s)	ACG Status			
	Member in Training	Member	Fellow	Year
Principal Investigator				

FUNDS REQUESTED: \_\_\_\_\_

NAME OF RESPONSIBLE INVESTIGATOR: \_\_\_\_\_

(to be completed if Principal Investigator is a trainee)

## IRB STATUS:

Approved	Pending	Approval Not Required

## CONFLICT OF INTEREST:

None	Potential	Yes

## CONSIDER FOR BOARD OF GOVERNORS' AWARD?:

Yes	No

*As the principal (or responsible investigator, if applicable), I agree that if this grant proposal is funded, I will acknowledge the ACG's support in all publications that arise from the research. I also will submit to the ACG Research Committee a final report 18 months after the receipt of funding.*

Signature of Principal Investigator: \_\_\_\_\_

Signature of Responsible Investigator (required if Principal Investigator is a Trainee) \_\_\_\_\_

Institution and mailing address (include phone and fax numbers and e-mail): \_\_\_\_\_

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