



Research Foundation American Society of Colon and Rectal Surgeons

85 West Algonquin Rd., Suite 550, Arlington Heights, IL 60005
(847) 956-1846 Fax: (847) 290-9203 Website: <http://www.fascrs.org>

**RE: ASCRS Research Foundation
RFP – Clinical Studies on Benign Colorectal Disorders**

Dear Colleague:

Please review the following requirements carefully. All requirements must be adhered to or the application will not be considered.

The Research Committee of the Research Foundation of ASCRS will make every effort to perform a comprehensive review of your application in an expeditious manner. This review may require assignment of appropriate expertise from the scientific community outside of the colon and rectal surgical field.

If you have any questions, please call the Research Foundation office at 847-956-1846.

Mail 2 completed applications (on 3-hole punch paper)
and a copy on CD to:

Ronald Bleday, MD, Chairman, Research Committee
RESEARCH FOUNDATION OF ASCRS
85 W. Algonquin Road, Suite 550
Arlington Heights, IL 60005-4460

Sincerely,
Ronald Bleday, MD
Chairman, Research Committee

Request for Proposals (RFP)
for
Clinical Studies on Benign Colorectal Disorders
Criteria

Funding: \$50,000 per year for 2 years

Application Deadline: October 1

I. Purpose:

Through the RFP Program, the Research Foundation intends to encourage the conduct of well designed clinical trials leading to a definitive answer to a specific colorectal program. The goal of the Research Foundation's RFP program is to foster outstanding research in specific areas of colorectal diseases or disorders leading to the improvement and management of common, yet understudied colorectal problems. Pilot studies or phase I, II, or III trials are all appropriate clinical study designs. A peer review mechanism with emphasis on scientific merit will be used to rate proposals.

II. Eligibility Requirements:

- The proposed research must be hypothesis-driven and investigator-initiated
- The proposed research must be conducted within the United States or Canada
- ASCRS member must be the Principal Investigator or a Co-Principal Investigator

III. Award Provisions:

- The number of RFP grants and the level of funding will be determined by the Board of Trustees of the Research Foundation annually.
- The award may be funded in whole or in part.
- The award need not be given every year.
- Second year of funding is contingent upon approval of interim report at nine months of funding.
- Funds are for direct costs only and are intended to establish new studies.

IV. RFP Topics

The RFP Program is targeting the following benign colorectal conditions as listed in alphabetical order:

- Anastomotic Leak (roles of new technologies in reducing leak rate)
- Anorectal Surgery (reduction of post-operative pain)
- Conservative management of diverticulitis (may involve a trial to determine appropriate role of percutaneous drainage of diverticular abscess or a trial of surgery versus observation after recovery from diverticulitis or other similar trial ideas)
- Drain versus no drain after low anterior resection
- Parastomal Hernias (optimal techniques and best preventative method)
- Simple and Complex Anal Fistulae (optimal surgical & medical treatment)

V. Application and Monitoring Process

- A one page **letter of intent** to apply for an RFP grant should be submitted to the Chairman of the Research Committee by **September 1st**. The letter should include a brief description of the proposed project and the principal investigator or co-investigators.
- You should submit your proposal to your **local Institutional Review Board** prior to submission of the application as IRB approval is required at time of grant submission. Time to obtaining IRB approval varies and may be time consuming, so plan ahead.
- The full **grant application deadline is October 1**. This must include a detailed budget and an official IRB letter of approval.
- An **interim progress report** at a nine month interval after receiving the funding is necessary to secure the second year of funding
- A detailed **final report** of analysis and conclusions of related presentations and publications derived from the funded study will be required.

VI. Funding Priority

Funding is based upon scientific merit review by the Research Committee with special consideration given to applications perceived to have a high likelihood of success and impact on the practice of colon & rectal surgery.

Research Foundation of ASCRS

Supplemental Guide To Grant Application

Section 1

The instruction book that is part of PHS-398 provides detailed information on each item and/or section of the grant application. The additional comments that follow are not meant to replace any portion of PHS-398. They are intended rather to emphasize certain aspects that are frequently inadequately addressed or overlooked entirely.

It must be remembered that even the best, most intriguing and worthwhile appearing concept or hypothesis cannot be funded just because it is a great idea. It is up to the principal investigator to support the feasibility of the concept as well as to produce a document that as written stands a reasonable chance of producing a definitive answer. It is not up to the Research Committee to fill in the blanks even if they are obvious. The Research Committee wants to fund projects, but it is up to the principal investigator to conceive of, design, and execute the project.

A. What is the Question?

This must be stated up front in the Description and the Specific Aims section of the Research Plan. This must be supported in the Experimental Design and Methods section. This drives the whole proposal and must be concise, focused, feasible, and never lost sight of. The endpoints of the investigation should be clearly stated in the question.

For example: Are increased body iron stores as measured by serum ferritin associated with increased risk for developing colorectal adenomas?

And not: We intend to do anorectal manometry in patients with fissure in ano.

In general, an hypothesis should be stated and the approach and rationale to prove or disprove the concept should be the driving force throughout the proposal.

The fact that this is research assumes that the answers are not known ahead of time. Consequently, it is very reasonable to accept that the concept, the hypothesis, may in fact be wrong. Under such circumstances, it must be clear that being wrong can be proven just as readily as being correct. Consequently, it is important that the principal investigator indicate the alternative possibilities that might result from this research and the response that might be taken as a result of having to change direction. Are potential pitfalls recognized?

B. Data

What specific data will be collected to answer the question? How will it be collected? How will it be analyzed? You must show in advance that you know how to process the data that you propose to collect.

C. Power Analysis

Not all projects depend upon a sufficient number of patients or subjects in two or more categories to reach a conclusion. However, when conclusions hinge upon the results of one group versus another, then evidence has to be provided to support the likelihood that the project as designed, with the study patient population available, is likely to meet the desired objectives.

Will the study as designed answer the question that you have asked? This is a critical question. Of first importance is, of course, the solidity of the experimental method. Next is the sample size. We are all aware of tests of significance, “p” values, chi squares, “t” tests and ANOVAs. These are not interchangeable and the proper methodology must be specified. Type 2 or beta error and the power of study are just as important statistics and must be examined in the formulation of the study rather than after data collection is over. A study without adequate power is a waste of money for a funding agency. Power calculations must be provided.

It is inappropriate to state: “data will be analyzed by computer” or “the statistical consultant will analyze the data”.

D. Facilities

Do you have access to enough material to answer your question? This is not just a calculation, but your chance to assure the granting body that you, for instance, see enough patients with a particular disorder to achieve adequate statistical power. If the proposal relates to fissure in ano and your power calculations show that 150 subjects will be needed for the study, you must review the records for your institution to prove that that many eligible patients with fissure are seen within the study period.

E. Human Subject Studies

Think of the ethical pitfalls of the study. Remember that research and therapy are two different things. Randomization into one of two or more treatment groups implies that less than optimal therapy may be given for the sake of research. Do your patients know this? What specific risks are involved in the research protocol? Even if one arm is standard therapy, the risks of that therapy must be delineated. The consent form for participation must be included with the proposal and, for obvious reasons, be entirely different than a standard operative consent. To state in the Human Subjects section only that IRB approval is pending is inadequate. The Foundation is not an IRB, but it must be assured that you have seriously considered the ethical side of your proposal.

The same goes for animals within that specific context.

F. Get Help

The essence of research is communication. Let it begin within your institution and/or society. You wouldn't think of doing your first APR without any assistants, scrub nurses or anesthesiologists. Nor even your 100th. A well kept secret is that experienced investigators become progressively more interdependent upon their colleagues in various disciplines in formulating their ideas, hypotheses and grant proposals. Isolation is a rather sad sign of inexperience that is quite apparent in reviewing grant proposals.

G. Don't Assume that the Reviewers of Your Proposal have any Imagination

Do not assume that your reviewers will go to the library in order to read all your cited references as part of the review process. The Background and Significance section must be brief, but self contained. The physiologic principles relating to your proposal must be explained, rather than just cited. The literature review need not be global, but must be up to date, concise and relevant.

H. Budget

This isn't the Department of Defense. A carefully thought out budget with each item clearly justified will add great strength to your application. There's no magic to this. You are setting up a small business and should expect to be as careful in planning your expenses as you would with a bank loan (though it is unusual for the Foundation to ask for collateral or second mortgages). Travel funds that are intended for meeting presentation of research data are unlikely to be approved. Consultant items must be specifically justified. Substantial hardware items, particularly purchases related to computer equipment, are unlikely to be covered by the budget. This is particularly true if the specific item has a strong likelihood of subsequent payback based on clinical services.

Contractual agreements with other institutions or parties must be included.

I. Limitations of the Study

This is your chance to anticipate your reviewers and nip their questions in the bud (rather than hoping against hope that they won't ask any). Describe your perception of the weak points in your proposal and what specific steps you have taken to strengthen those points.

J. Above All: Remember, What is the Question?

Ronald Bleday, MD
Chairman, Research Committee
Research Foundation of ASCRS

Section 2

Research Foundation American Society of Colon and Rectal Surgeons Grant Application Guidelines

Please use the NIH, PHS 398 forms available at <http://grants1.nih.gov/grants/forms.htm>

Be sure to include:

Face page

Description, Performance Sites, and Personnel

Table of Contents

Detailed Budget for Initial Budget Period

Budget for Entire Proposed Period of Support

Budgets Pertaining to Consortium/Contractual Arrangements

Biographical Sketch

Resources

Other Support: Please list support you will receive for this project from any other sources including government, non-government, and institutional. If none, state “none”.

- 1) active support
- 2) applications or proposals pending review of funding
- 3) applications and proposals planned on being prepared for submission.

Research Plan:

Include sufficient information in this section to facilitate an effective review without reference to any previous application. Be specific, informative, and avoid redundancies. Brevity and clarity are encouraged.

Organize Sections A-D to answer these questions:

- a. What do you intend to do?
- b. Why is the work important?
- c. What has already been done on this subject?
- d. How are you going to do the work?

A. Specific Aims:

Concisely in one page outline what the research described in this application is intended to accomplish and/or why hypothesis is to be tested.

B. Significance:

Briefly outline background material to the present proposal, critically evaluate existing knowledge, or identify why your visit to a particular institution or institutions is important. State concisely the importance of the research by relating it to specific long-term objectives. Do not exceed three pages.

C. Progress Report/Preliminary Studies:

A progress report following the first six months will be required. Give the beginning and ending dates for the period being reviewed. List all professional personnel who have worked on the project with you during this period, their titles, and organization. Provide a succinct account of what has been accomplished during this time period, and review the importance of these accomplishments. Discuss any changes in the specific aims since the project was last reviewed. List titles and complete references to all publications, manuscripts, inventions, speaking engagements or any printed material that has resulted from the project.

Submit this report to the Chairman of the Research Committee of the Research Foundation. Include supplementary graphs, diagrams, tables and charts relevant to the project with each copy.

D. Experimental/Project Design and Methods:

Discuss in detail the experimental design or outline of your research and the procedures to be used to accomplish the specific aims of the project. Describe protocols to be used and provide a tentative sequence or timetable. Include means of data analysis and interpretation.

Describe any new methodology and its advantage over existing methodologies. Discuss potential difficulties and limitations of your project, and possible alternatives to achieve your aims. Make every attempt to be succinct in this section, and do not exceed 8 pages.

E. Human Subjects:

If you intend to use human subjects during your project, but not in an experimental nature, follow only instructions as outlined below. If subjects in this experiment or project will be subjected to experimental medication or techniques, please be sure to include certification by the institutional review board with this application.

1. Describe the characteristics of the subject population, e.g. anticipated number, age ranges, sex, ethnic backgrounds and health status. Identify criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects.
2. Identify sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.
3. Describe plans for recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of information to be provided to prospective subjects and the method of documenting consent. The consent form must have institutional review board approval.
4. Describe any potential risks – physical, psychological, social, legal, or other – and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
5. Describe procedures for protecting against, or minimizing any potential risks, including risks of confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for insuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring data collected to insure the safety of subjects.
6. Discuss why the risks to subjects are reasonable in relation to anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

F. Vertebrate Animals:

If vertebrate animals have been identified on page 2 of the application, justify their use, state the species, strains, ages, and numbers of animals involved. Describe procedures for adequate maintenance and veterinary care of any animals. Describe procedures to avoid unnecessary discomfort, pain, or injury to the animals, such as surgical anesthesia, post-trauma analgesia, tranquilizing drugs, and comfortable restraining devices.

G. Literature Cited:

Please list all citations of literature at the end of the research plan. Each complete citation must include the names of all authors, the complete title of any article, the name of the book or journal, volume number, page numbers, and year of publication. Please compile a relevant and current bibliography. It need not be exhaustive.

H. Consortium/contractual arrangements.

I. Consultants.

J. Appendix.

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c/o ASCRS Research Foundation
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