

Research Foundation of the ASCRS Limited Project Grant

I. Introduction

The primary mission of the Research Foundation of the American Society of Colon and Rectal Surgeons is to raise and award funds to support research and educational programs related to colon and rectal diseases. Over the past twenty years, the Research Foundation has awarded over 120 grants and \$4 million to colorectal surgeons and researchers to investigate a broad spectrum of colorectal diseases and to develop novel surgical techniques pertinent to the care of colorectal patients.

II. Limited Project Grant Overview

Purpose: To provide investigator the opportunity to pursue research interest, specifically germane to the field of colon and rectal surgery. It is anticipated that successful research projects, initially funded through The American Society of Colon and Rectal Surgeons Research Foundations' LPG mechanism, will ultimately secure funding from other national funding agencies.

Funding: Up to \$50,000 for 1 year.

- LPG need not be given every year.
- LPG award may be funded in whole or in part
- No consortium/contractual arrangements will be allowed with collaborating organization
- Salary support for the Primary Investigator is not permitted
- LPG funding is limited to "Direct Cost Only" budgets. Additional indirect costs will not be approved.

Application Deadline: November 1

Funding: Spring

Topic: The purpose of the Research Foundation of the American Society of Colon and Rectal Surgeons is to promote research that relates to the practice of colon, rectal and anal surgery. In order to maintain a portfolio of funded LPGs that address the broad field of colon and rectal surgery, no specific area of inquiry (topic) is emphasized, nor preferentially funded. Clinical and basic science projects will be considered on their own merits.

Application Process: Research project applications to the Research Foundation of ASCRS are made on Public Health Service grant application form PHS 398. The PHS grant application process has had a long history of satisfactory operation. By using PHS 398, the process of renewal or extension to subsequent Research Foundation or NIH funding, if applicable, will be facilitated. The Research Committee of the Research Foundation 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 contact the Research Foundation office at rf@fascrs.org or (847) 956-1846.

III. Award Eligibility

- The proposed research must be investigator-initiated, hypothesis-driven
- The proposed research must be conducted within the United States or Canada
- At least one ASCRS member must be principal investigators or co-principal investigators
- Primary investigator must have a faculty position and be post graduate from clinical and research training.
- Prior to submitting your application, any proposed research that includes human or animal studies must have approval from the institutions appropriate review board.

IV. Preparing Application Materials

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

Format: Use the NIH continuation pages on the ASCRS or NIH websites.

- Fill in your name on all pages.
- Number all pages
- Use Arial or Times New Roman font
- Minimum font 11pt
- Margins: top 1", sides 0.5", bottom, 0.75"
- Single spaced

Include only the following pages from the PHS 398 in sequential order:

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: Biographical sketches are required from applicant, and all co-investigators. Use the NIH biosketch form and follow the instructions/format provided on the NIH website. (Biographical sketches should be no greater than five (5) pages in length. Be sure the appropriate page numbers are at the bottom.)

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". Include for each percent overlap

with the current proposal. Use a continuation page for this and entitle it "Other Support."

- Active support
- Applications or proposals pending review of funding
- Applications and proposals planned on being prepared for submission

Conflict of Interest Statement: Include a disclosure statement for any potential conflict of interest related to this research proposal. If there are no potential conflicts, please submit a statement stating, "there are no conflicts of interest to disclose".

Standards for Commercial Support require that you disclose any relevant financial relationships with commercial interests. The Research Foundation defines a "commercial interest" as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The Research Foundation does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, a Research Foundation- defined commercial interest.

Research Plan (Sections A – J)

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 the following sections A-D to answer these questions:

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

A. Specific Aims/Hypothesis:

 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. State concisely the importance of the research by relating it to specific long-term objectives.
- Do not exceed three (3) pages.

C. Preliminary Studies:

- Briefly outline any preliminary studies you have performed that support your hypothesis and/or demonstrate your ability to perform the methods described below.
- Do not exceed two (2) pages.

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.
- Do not exceed eight (8) pages.

E. Human Subjects – If you intend to use human subjects during your project follow only instructions as outlined below. Be sure to include certification by the institutional review board from your institution with this application, and describe the following:

- 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.
- 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.
- 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.
- 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.
- 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.
- 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:

o 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. Provide evidence of Animal Welfare Assurance from your institutions Animal Care Committee must be submitted with your application.

G. Literature Sited

- Please list all citations of literature at the end of the research plan, in the order in which they are cited in the proposal. 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.

V. Submitting Application Materials

Applications must be submitted in ONE PDF file including all components listed in the table of contents no later than 11:59 pm on November 1st to rf@fascrs.org

VI. Application Review

The Research Foundation of the ASCRS Research Committee reviews all completed applications received by the deadline through a peer review process. The committee is composed of funded researchers who are members of the ASCRS. Members of the committee serve pro bono and do not participate in evaluation of applications from applicants or institutions in which there is a conflict of interest.

VII. Re-Submitting a Limited Project Grant

If you have previously submitted an LPG that was not funded. You may re-submit the same application during the next submission cycle. Re-submissions must adhere to the following:

• Indicate that your application is a re-submission in your cover letter and write "re-submission" in the upper right-hand corner of your application.

- Highlight all aspects of the application that have been altered from the original submission. Electronic and paper copy must be highlighted.
- Include the letter from the Research Foundation indicating what needed to be altered in your original LPG application.

VIII. Expectations of Awardees

The purpose of the LPG is to promote the research and development specifically germane to the field of colon and rectal surgery. This represents a significant investment by the ASCRS Research Foundation. In return, LPG recipients are expected to:

- Submit funded research to ASCRS annual meeting for presentation
- Submit funded research to DC&R for consideration of publication (include a statement acknowledging that the work was funded by a Limited Project Grant through the Research Foundation of the American Society of Colon and Rectal Surgeons in all published manuscripts pertaining to work outlined in the proposal.)
- Provide a mid-term progress report six (6) months after initiation of the award.
- Provide a research report within three (3) months of completion of the funding period.
- Ultimately become active members of ASCRS (serve on committee, journal reviewer, etc.)

IX. Preparing a Mid-term Report

Please send mid-term report six months of initiation of the award (1-2 pages in length at most).

- 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 periods, 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
- Include supplementary graphs, diagrams, tables and charts relevant to the project with each copy

X. Preparing a Final Report

Please send a final report within sixty days of the award completion including the following elements (1-2 pages in length at most):

- Restate the specific aims/goals of your research plan and demonstrate the result toward each aim/goal. Include all supporting data.
- Indicate any deviations you have made from the original research plan and justify these changes. If you did not reach one or more of you initial goals, explain why.

- Indicate any problems or delays that you have encountered; for example, problems in obtaining protected time to do research, slow patient accrual in the study, etc.
- Prepare a list of your articles, chapters and abstracts that have resulted from your project. Please separate abstracts, peer-reviewed manuscripts, reviews and presentations. Indicate "published, in press, submitted, or presented" for each item and *enclose copies*.
- Indicate if the result from your studies will be used as preliminary data in a grant application to another granting agency.
- Indicate the clinical significance and future clinical impact of the results of you study. Indicate if you received adequate institutional support.
- Final reports are posted on the ASCRS website grant pages. Please indicate if you do not wish to have your final report included in such posting.
- A financial report must be submitted at the same time as the final report with a complete
 financial accounting of all ASCRS funds expended over the entire life of the project including a list
 of assets and any equipment purchased with these funds and any travel expenses associated with
 the award. Please indicate how the expenditures relate to the project.

XI. Applying for a Competing Continuation (2nd year of funding)

All Limited Project Grants are a one-year award. However, a competing continuation for one(1) year may be submitted.

- Request must be submitted four (4) months prior to the end of the award year.
- The initial application should stand on its own merit
- If a competing continuation is anticipated, the research plan on the initial application should specifically and separately outlining what work would be performed during a possible continuation year.
- The "Budget for Entire Proposed Project Period", "Direct Cost Only" and "Check List Forms" should include the anticipated competing continuation year.
- Failure to indicate an anticipated competing continuation will not interfere with such application if it is subsequently submitted.

Please submit Renewal requests and Final Reports to: rf@fascrs.org

XII. Grant Writing Suggestions

The following bullet points provide some helpful suggestions for grant applicants. The comments are based on many years of experience reviewing grant applications by the members of the Research Committee.

The Research Committee is anxious to provide funds for researchers but is very clear that its mandate is to only support the best quality applications. The members of the committee are all experienced grant reviewers, recognized independent investigators, or both. All applications will receive a thorough and

critical review and applicants will receive the verbatim review comments whether or not the application is funded.

Planning and Writing the Grant Request:

- Start early and meet the deadlines. Allow plenty of time to put the application together.
- Read the instructions.
- Follow the instructions.
- The Research Committee likes to see thoughtful writing and planning. Grants that are hastily put together, have grammar/spelling errors, or don't make sense are not funded.
- A common rule of thumb for many experienced grant writers is to have a final draft of the grant completed at least a month prior to its deadline. Ask for a respected colleague not involved in the work to critically review and proof the grant prior to submitting.
- Write the grant so that it is readable. Make the font large enough to be comfortably read. Make
 the content understandable for someone who is not an expert on your topic. The more
 understandable the grant, the better the review will be, and if everything else is equal, it will
 more likely be funded. If you take excerpts from a paper, make sure the tenses match. Make sure
 the separate excerpts flow well.
- Read carefully and avoid typos, these create concerns that your work is sloppy.
- Don't copy another person's grant. It usually shows. If you must take excerpts from another grant, make sure the fonts match.
- Tell us why this work is important and what it might lead to.
- Have a specific overall hypothesis that asks a specific question. There should also be a hypothesis for each specific aim. Be very clear about what your hypothesis is.
- Provide preliminary data if allowed. Preliminary data can be of 2 types: data that supports the hypothesis or data that may not be relevant to the grant but shows that you can perform a technique (especially a difficult one). Tell the reader how the preliminary data supports your application, and don't make the reviewers figure it out.

Letters of Support:

- Read your letters of support if possible. Make sure that you get the pertinent letters of support from the colleagues involved in the study and appropriate mentors as required.
- Make sure the letters have your name and the title of your project correctly identified.
- Make sure the writer knows something about the project and that the letter reflects that understanding.

Timeline, Resources, Budget, and Results:

- Make a timeline of the study grant to go along with the proposal.
- Make sure the project is feasible, including the funds, the time period, and the personnel. The methods section is very important in this regard.
- Make us believe that you can actually do the work you say (show us how you have the resources, the track record, the expertise, and the time).
- Make sure the budget is appropriate for the grant.

- If your proposal will cost \$40,000 and the grant is only for \$30,000, explain where you are going to get the extra \$10,000 (department funds for example) if you are funded.
- Make sure the budget is reasonable. The review committee has an idea of what things cost so embellishing the figures is not wise.
- Tell the reader what you expect the results to be.

Helping the Reviewers Understand Your Grant Request:

- Don't assume reviewers are thoroughly familiar with the literature in your specialized field.
- Don't assume reviewers are familiar with the validity of all of your experimental techniques as they pertain to the area being studied. Cite literature that supports that your technique will reliably answer your question.
- Help the grant reviewers understand the significance of the grant proposal. Why is your project so important to fund? Do not assume the reviewer will understand. Make it crystal clear.
- Think like a reviewer. Identify the challenges, limitations, biases, and then address them as best as possible. The more these issues are addressed, the better. Tell the reader what alternatives you will try if your proposed experiments don't work.

Animal Subjects and IRB Approval:

- When using animals in experiments, a chart that shows the animal groups is often helpful.
- When using animals make sure that you accurately count how many you will need based on the experiments proposed.
- Have the appropriate animal or IRB approval that the instructions request (some grants require approval; some grants accept "pending approval").
- Don't forget that animals have housing and shipping costs in addition to purchase.

Resubmission of Your Grant Request:

- When submitting a revised grant, make sure the changes that are made in response to the critiques are absolutely clear. Use the comments of the reviewers to strengthen your rejected grant for the next application cycle.
- Note on the revised grant that it is a resubmission.

Finding the Right Grant-giving Organization:

- Do a thorough check of granting organizations to arrive at one likely to be interested in funding you.
- The Research Committee is anxious to help applicants succeed, however all decisions are final. Applicants are welcome to resubmit their applications for the next LPG application review.

Suggested Reading:

Consult the book "Grant Application Writer's Handbook" by Liane Reif-Lehrer, Jones and Bartlett Publishers, International, Boston, London. This is a well-written, clear and concise guide to grant writing.

"The Grant Application Writer's Workbook - Guide to a Successful Proposal" for the NIH (and any other public health service agency for the PHS SF424 application guide (04/2006). The authors are Stephen W. Russell and David C. Morrison, of Grant Writers' Seminars and Workshops, LLC. The URL is http://www.grantcentral.com. While this won't help with the subject choice or the hypothesis, per se, perhaps it will help with the level of content, organization, and structure.

Sincerely, Elizabeth Wick, MD Chair Research Committee