



General Surgery Resident Research Initiation Grant

Preparing Application Materials:

Research project applications to the Research Foundation of ASCRS are submitted based 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.

Applicants will be asked to enter or upload the following information in the web-based portal (list is not inclusive):

Step 2: Title/Body

- **Title of Project**
- **Research Plan** (A. Specific Aims/Hypothesis; B. Significance; C. Preliminary Studies; D. Experimental/Project Design and Methods; E. Human Subjects; F. Vertebrate Animals; G. Literature Sited; H. Consortium/contractual arrangements; I. Consultants; J. Appendix). ([PDF Upload](#))
 - Be specific, informative, and avoid redundancies. Brevity and clarity are encouraged. This should be a maximum of five pages, excluding references.
 - Organize 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.
- C. **Preliminary Studies:**
 - Briefly outline any preliminary studies you or your mentor has performed that support your hypothesis and/or demonstrate your ability to perform the methods described below.
- 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.

- 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 ensure 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:
- 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.
- 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.

- [Human Subject Research](#) (no/yes)
- [Research Exempt](#) (no/yes – if yes, exemption no.)
- [Federal-Wide Assurance Number](#) (no/yes – if yes, exemption no.)
- [Clinical Trial](#) (no/yes)
- [NIH-defined Phase III Clinical Trial](#) (no/yes)
- [Vertebrate Animals](#) (no/yes - animal welfare assurance no.)
- [Dates of Proposed Period of Support](#)
- [Costs requested for initial budget period](#)
- [Costs for proposed period of support](#)
- [Administrative official to be notified if award is made](#) (name, title, address, telephone, fax, and email)

- [Type of Organization](#) (public, private, for-profit, woman-owned, socially, and economically disadvantaged)
- [Entity Identification Numbers](#) (Entity Identification Number, DUNS Number, Cong. District)
- [Official Signing for Applicant Organization](#) (name, title, address, telephone, fax, and email)

Step 3: Properties

- [Other Support](#): It is anticipated that applicant will seek matching/complementary funding from department of origin and/or mentor. Institutional supplementation of salary must not require extra duties or responsibilities that will interfere with the purpose of the grant.
- [Budget Justification](#). Include a summary outlining the budget for this project. This should give the reviewer a good idea of what expenses the proposal is meant to cover as well as additional expenses not expected to be paid by other sources.
- [Detailed Budget for Initial Budget Period](#) ([PDF Upload](#))
- [Budget for entire Proposed Period of Support](#) ([PDF Upload](#))
- [Letter from Research Mentor](#). If more than one letter, compile into a single PDF for upload. (PDF Upload)
 - Mentor to provide a summary of applicant's qualifications as well as anticipated role mentor will play in assuring a successful completion of the proposal. A specific plan for mentorship should be included demonstrating commitment to career development of the applicant. The letter should cover the following.
 - Approval of research proposal and assurance of space and supplies needed
 - Mentor's qualification in the research area proposed by the applicant
 - Previous experience as a research mentor
 - Address the candidate's potential and his/her strengths and areas needing improvement
 - Nature and extent of supervision that will occur during the award period:
 - Include a detailed mentorship plan that describes how the mentor will monitor and evaluate the applicant's progress toward independence
 - Include specific milestones during the award (completion of coursework and submission of manuscript)
 - Resources the mentor will make available to the applicant in support of their training
 - *Co-mentors should provide letters with similar information outlining the respective areas of expertise and how the shared mentoring of the candidate will be coordinated. External mentors should document the mechanism of communication with the candidate including the frequency of remote and face-to-face meetings.
- [Is the Research Mentor a Fellow of the ASCRS?](#)
- [Letter from an ASCRS Fellow](#). If more than one letter, compile into a single PDF for upload. (PDF Upload)
 - Required only if the Research Mentor is not a Fellow of the ASCRS. Preferably from someone that has a personal and/or professional familiarity with the applicant and can speak to applicant's ability to successfully perform and complete the proposed research.
- [Letter from Chairman of the applicant's department or responsible superior](#). If more than one letter, compile into a single PDF for upload (PDF Upload)
 - Provide evidence for departmental and institutional support for applicant's research proposal. This should include a specific description of proposed protected time, lab space, and necessary support personnel as may reasonably be required to pursue and/or complete the research proposal

Step 4: Applicants

- [Senior/Key Personnel and Other Significant Contributor](#)
 - Conflict of Interest Statement/Disclosures
 - Affiliation
 - Role on Project (principal investigator, co-principal investigator, co-investigator, mentor, co-mentor, collaborator, researcher, statistician, other)
 - Major Subdivision

- eRA Commons Username
- **Biographical Sketch.** Biographical sketches are required from applicant, mentor, and all co-investigators. Compile all biographical sketches into a single PDF for upload. ([PDF Upload](#))
- **Career Goals and Objectives** (description of career goals and how funding will help applicant attain them, 250-word limit).

Step 5: Disclosures

- **Applicant Organization Certification and Acceptance** (applicant organization hereby represents, warrants and acknowledges, required)
- **IRB Approval.** Compile all documents into a single PDF for upload. ([PDF Upload](#))
 - Evidence of IRB approval is necessary for all human subject research. If you have questions about your specific proposal and if this applies to you, please [email](#).
 - IRB approval for human studies is important; unapproved studies can cause delays. To that end, the absence of an IRB at the time of submission will be taken into consideration by the Research Committee during the grant review.
- **Resubmission of Grant Request** (yes/no – yes, upload document highlighting all aspects that have been altered, including the letter from the Research Foundation indicating what needed to be altered from the original submission)

Step 6: Review & Submit

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