

Eugene Salvati, MD, Limited Project 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):

When submitting required application support documents for consideration, kindly ensure that all documents are consolidated into a single PDF. Applications without proper inclusion of the required support documentation in the specified order and format may regrettably not be reviewed and considered for funding. Thank you for your understanding and adherence to the submission guidelines.

Required documentation must be in the following order and the PDF will be uploaded in Step 5: Disclosures of the application.

- *Project Summary*
- *Relevance*
- *Research Plan*
- *Budget for Entire Proposed Period of Support*
- *Biographical Sketches*
- *IRB Approval, if applicable*
- *Vertebrate Animals, if applicable*
- *Resubmission of Grant Request, if applicable*

Step 2: Title/Body

- **Title of Project**
- **Project Summary** (PDF upload; Limit to 500 words): The project summary description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other people working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.
- **Relevance** (PDF upload; Two/Three sentences): Describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.
- **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 Cited). (PDF Upload)

- Preparing Research Plan Document: name on all pages, numbers on all pages, use Arial or Times New Roman font, minimum font 11pt, margins: top 1", sides 0.5", bottom, 0.75" and single spaced.
 - Be specific, informative, and avoid redundancies. Brevity and clarity are encouraged.
 - 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.
 - Do not exceed three (3) pages.
- 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.
 - 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 briefly 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 in 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. Briefly 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. Documentation must be submitted with your application.
- G. Literature Cited
 - 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.
- [Identify Type of Research](#) (Basic, Translational, Clinical, Health Services or Other)
- [Administrative official to be notified if award is made](#) (name, title, address, telephone, fax, email and organization)
- [Official Signing for Applicant Organization](#) (name, title, address, telephone, fax, email, and organization)

Step 3: Properties

- [Other Support](#): List support that will be received from any other sources including government, non-government, and institutional. If none, state “none”. Include for each percent overlap with the current proposal. (Active support, Applications or proposals pending review of funding, Applications and proposals planned on being prepared for submission)
- [Budget for entire Proposed Period of Support \(PDF Upload\)](#)
 - Salary support for the Primary Investigator is NOT permitted.
 - Funding is limited to “Direct Cost Only” budgets. Additional indirect costs will not be approved.

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
- [Biographical Sketch](#). Biographical sketches are required from senior/key personnel and other significant contributors (i.e., principal investigator, co-investigators, mentor, collaborator). Biographical sketches should be no greater than five (5) pages in length. Be sure page numbers are at the bottom of each page.
 - Compile all biographical sketches into a single PDF for upload. ([PDF Upload](#))

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.

- **Vertebrate Animals**
 - Evidence of Animal Welfare Assurance approval is necessary for all projects where live vertebrate animals are involved. If you have questions about your specific proposal and if this applies to you, please [email](#).
 - Evidence of Animal Welfare Assurance approval is important, unapproved studies can cause delays. To that end, the absence of an Animal Welfare Assurance number 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

- DON'T FORGET TO CLICK THE SUBMIT BUTTON. If you exit the system without submitting, the submission will appear in the "Draft" section of your "View Submissions" page when you re-enter the system.

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