



PLASTIC SURGERY
EDUCATIONAL FOUNDATION

Plastic Surgery Educational Foundation

ASRM/PSEF Combined Pilot Research Grant

Eligibility and Grant Application Guidelines

Submission deadline: December 15, 2009

All Applications must be submitted online through proposalCENTRAL.
Please visit the ASPS/PSEF website for the proper link to this application in proposalCENTRAL.

Combined Pilot Research Grant Program Eligibility

Applicants must be a MD, DO, PhD or in training. Applicants must be an ASPS or ASRM member or candidate member. If you are currently in your training, you may still apply to the program with sponsorship from an ASPS or ASRM member or candidate member.

Applicants may submit more than one grant application if the projects are scientifically different. Only one project will be funded per applicant.

The following criteria shall apply to this award:

Amount: Up to \$10,000 United States Dollars for a one-year project to support the preliminary or pilot phase of scientific research projects. No salary support for the Principal Investigator will be provided.

The project is to be completed within the twelve (12) months following the receipt of the award. The Principal Investigator must provide PSEF with progress reports during the year. The first report is due at six (6) months and the second report is due at twelve (12) months.

The Combined Pilot Research Grant is not transferable to another individual within the Institution and not transferable to another institution OR to operating funds. If the Principal Investigator leaves the Institution, the Principal Investigator and the Institution must notify PSEF within thirty (30) days and all unused funds must be returned.

Appropriate and complete IRB/IACUC approvals must be on file in the PSEF Executive Offices within ninety (90) days of written notification of the Combined Pilot Research Grant Award. If the approval is not on file within the ninety (90) day time frame, the Combined Pilot Research Grant Award will be rescinded by PSEF. All annual renewals of IRB/IACUC approvals must be sent to the PSEF Executive Offices within thirty (30) days of receiving such renewal.

The Principal Investigator or faculty member applicant must provide an institutional assurance or documentation indicating specifically that the resources are available to execute the research plan for projects that require the use of laboratory or animal facilities.

Funding for this program will be made available **July 1**.

Prepare the application as if you were preparing an application to the NIH with the following essential alterations:

- A) Limitation on font size and document length:
- the minimum acceptable font size is 11 (Arial or Helvetica; no condensed fonts).
 - the maximum number of lines per inch is 6, **DO NOT PACK LINES BY SETTING LINE SPACING AT “EXACTLY”**.
 - for all continuation pages, the top, bottom, left, and right margins should be set at 0.75”.
- B) Be sure to adhere to the following limitations and suggestions, for each section of the Application.
- Face Page: After completing your application in **proposalCENTRAL**, you will need to print your Face Page (signature page) to retrieve your institutional signatures. Once you retrieve all signatures, please convert your Face Page to PDF and upload to your application in **proposalCENTRAL**. Please plan accordingly as obtaining the appropriate signatures may take time. Your grant submission will not be reviewed without institutional sign off. **Note on resubmissions** - resubmissions must be accompanied by a cover letter that summarizes the substantial additions, deletions or changes to the application. If you were provided a summary statement from your previous review, please also include a response to the issues raised in the summary statement.
 - Project Summary – not to exceed ½ page – This is the summary description of your research project. In language suitable for press release, describe the project’s broad, long-term objectives and its specific aims. Describe concisely the study design and methods, as well as the rationale, and techniques to be used to achieve the aims. In addition, in two or three sentences, describe the potential or real clinical impact this research is likely to have on the practice of plastic surgery.
 - Detailed Budget - complete all sections. Complete the Budget Justification Page immediately following your detailed budget. Please clarify and describe the purpose and need for each item listed on the Detailed Budget page, ie, Personnel, Consultant Costs, Equipment, etc. Under Personnel, please be sure to explain the role of each person in the project. A maximum of TWO pages may be used for the budget justification. **NOTE: Funding from the Plastic Surgery Educational Foundation (PSEF) does not support indirect or administrative costs. PSEF will not cover PI salary support for the Combined Pilot Research Grant.**
 - Biographical Sketch – Submit an NIH biosketch (not to exceed TWO pages) for ALL Key Personnel directly involved with the project. Include a biosketch for the Principal Investigator, Co-Investigators, Mentor, Sponsor and Collaborators. Research Fellows (who are not Co-Investigators or Collaborators) and Technicians do not need to include a biosketch. Expand the space for educational training if necessary. If you are omitting publications due to space limitations, include the statement: “The following publications were selected from among a total of _____ (#).” **DO NOT include publications ‘in preparation’ on this list.** For Item C. Research Support, list both completed and ongoing research projects for the past three years. Begin with projects most relevant to the research proposed in your application. In addition, please include a list of all past PSEF funded projects and any presentations or publications as a result.

- Resources – limit the description of resources available to those identified on the form.
- Other Support – Information on ALL active or pending support is required for both the PI and each Co-Investigator. Any scientific or budgetary overlap between funding, and/or other overarching projects should be clearly indicated and explained. Collaborators, Consultants, Research Fellows, and Technicians do not need to provide these pages. For individuals with no active or pending support, please indicate NONE.
- Narrative of Research Plan - Adhere carefully to the space limitations. The following sections in bold are to be addressed in the narrative.
THE ABSOLUTE PAGE LIMIT FOR ITEMS i TO iv COMBINED IS 10 PAGES, INCLUDING TABLES AND FIGURES.
 - Specific Aims** – This section should include a brief introductory paragraph. The introduction should give a brief overview of the project and state its significance and central hypothesis. Each Specific Aim shall be comprised of a title, central hypothesis, experimental approach and summary sentence. Please do not exceed ONE page for this section.

EX: The following is an example which follows the NIH format for the Introduction and Specific Aims.

I. Specific Aims

Approximately 46 million people in the US report that they have some type of physician diagnosed arthritis. Rheumatoid Arthritis (RA) is the second most common type reported, after osteoarthritis. A recent prevalence study reported by the National Arthritis Data Workgroup estimates that just under 1% of adults in the US have RA, which translates to 1.3 million people. RA affects people of all ages, but the prevalence is highest in the elderly population, affecting just over 2% of the population over age 60. With the overall aging of the US population, RA is going to be a continually growing problem. RA is a crippling disease. The joints of the hands are frequently involved, resulting in stiffness, pain, decreased function and deformity. There is no cure for RA and joint damage is progressive. Treatment of the rheumatoid hand aims to slow the progression of joint damage and restore pain-free function. Current management techniques range from therapy to medication to surgical intervention. Surgical interventions have been shown to be effective in reducing pain and restoring function. Despite surgical advances for the RA hand, there are large regional variations in the use of rheumatoid hand surgery, and a severe lack of consensus between hand surgeons and rheumatologists on the appropriateness and effectiveness of these procedures. Recently, a new class of biologic agents, Tumor Necrosis Factor (TNF) inhibitors, has been showing great promise in slowing or even preventing joint deterioration, particularly in the hands. The emergence of these drugs may further affect surgical management of the rheumatoid hand. The goal of this proposal is to examine the surgical treatment of the rheumatoid hand in the US elderly population by analyzing Medicare claims data. The Medicare database is the most comprehensive population database. It collects hospital, physician, and patient information relating to Medicare patients’ healthcare use. We plan to explore variations in surgical treatment over time and regions of the country, as well as changes specifically related to the introduction of TNF inhibitors. This will be the first population-based study on the utilization of hand reconstruction for the RA population, and the information gathered from this analysis will provide a greater understanding of the national variation in the treat-

ment of the rheumatoid hand. We will examine Medicare data from 1995 to 2006 to understand past and current treatments of this debilitating disease.

The specific aims for this project and their rationales are as follows:

Aim 1: To examine the current rates and past trends of surgical treatment of the rheumatoid hand in the US elderly population.

Rationale: No large national evaluation of hand surgery for RA has been conducted. We will examine surgical treatment rates as well as changing trends in the surgical treatment pattern of RA during the past decade from 1995 to 2004 using the 5% sample and from 2005 to 2006 using the 100% data.

Hypothesis: The use of rheumatoid hand surgery has decreased in the Medicare population over this 12-year period.

Aim 2: To identify changes in regional variations in the use of hand surgery for RA in the Medicare population.

Rationale: We have previously shown large variations in the use of rheumatoid hand surgery. We will examine surgical treatment rates (using the 5% sample from 1995 to 2004) by geographical region to explore the extent to which these utilization variations still exist.

Hypothesis: Regional variations have become less pronounced since our previous study because of greater awareness of the benefit of rheumatoid hand surgery.

Aim 3: To explore changes in rates of rheumatoid hand surgery since the introduction of TNF inhibitors.

Rationale: TNF inhibitors can drastically reduce the deterioration of joints in RA patients. We will examine surgical treatment rates before and after the FDA approval of the first of these drugs in 1998 by analyzing the 5% sample from 1995 to 2004. Hypothesis: The introduction of TNF inhibitors has resulted in the decreased use of rheumatoid hand surgery.

ii. Background/Significance and Preliminary Studies – For this section, please do not exceed FOUR pages. Please state your plan to test hypotheses and discuss the issues your project will address. Please identify relevant published papers and explain how your experiment will help resolve issues in the field of plastic surgery. Please present past work pertaining to your experiment and explain how your experiment will improve or build upon past outcomes.

iii. Research Design and Methods – For this section, please do not exceed FOUR pages. Concentrate on the DESIGN of the research, and explain why the methods chosen will suffice to answer your research question. Avoid technical minutia, instead, concentrate on the “big picture” of your plan, and use technical detail to argue the workability and soundness of your research plan. Please also include a detailed enrollment plan, should your study necessitate one.

iv. Data Analysis – Please do not exceed ONE page for this section. Please list all power calculations and statistical analysis proposed for your project.

v. Human Subjects – Include a summary of your safeguards for the use of human subjects, including specific references to adherence of accepted standards, and documentation of the project’s review by an appropriate IRB or hospital ethics board. **PLEASE LIMIT THIS SECTION TO ONE PAGE**, do not include the entire IRB application. Include copies of all Approval Letters

from the appropriate IRB Board(s), including BioSafety and/or Radiation Safety (if applicable). Upon receipt of approval, please upload this documentation to your application in **proposalCENTRAL (If applicable)**. **PLEASE NOTE: All complete IRB/IACUC approvals must be on file in the PSEF Executive Office within ninety (90) days of notification of award.**

vi. Vertebrate Animals – Include a summary of your safeguards for the use of animals in scientific research, including specific reference to adherence to accepted standards (e.g. NIH publication No. 86-23), and upload the documentation of the project’s review by the appropriate institutional committee, including BioSafety and/or Radiation Safety, to your application in **proposalCENTRAL** upon approval. **PLEASE LIMIT THIS SECTION TO ONE PAGE (if applicable)**. **PLEASE NOTE: All complete IRB/IACUC approvals must be on file in the PSEF Executive Office within ninety (90) days of notification of award.**

vii. Literature Cited – Please list all references in order of occurrence of their first mention in your proposal, in number or superscripted form. There is no page limit on this section.

viii. Leadership Plan – For applications proposing multiple PIs, a leadership plan is required. The governance and organization structure should be described, including communication plans and procedures for resolving conflicts. The shared administrative, technical and scientific responsibilities for the project or program should be delineated for the PIs. Please limit this section to ½ page.

ix. Consortium and Contractual Agreements – Describe all research relationships required for this project carefully. There is no page limit on this section.

Other Attachments

Sponsor Letter – An original letter from your ASPS or ASRM Sponsor must be submitted. This letter must verify that the trainee will be present and fully available to carry out the proposed work. Applicants, for which this eligibility requirement is not met, will not have their application reviewed. Please upload your Sponsor Letter as “Sponsor Letter” in the upload section of your application in **proposalCENTRAL**.

Letters of Support – All Co-Investigators and Collaborators must submit an original Letter of Support for their involvement in your research project. Please upload your Letters of Support as “Consultant/Collaborator Letters” in the upload section of your application in **proposalCENTRAL**.

Figures/Images – Please upload any/all figures or images as “Appendix” items in the upload section of your application in **proposalCENTRAL**. This may include, but is not limited to, any/all figures or images associated with your research plan.

Cover Letter for Resubmissions – If you are submitting a resubmission grant application, please upload your Cover Letter as “Cover Letter” in the upload section of your application in **proposalCENTRAL**. Note only those submitting a resubmission grant application must upload a Cover Letter.