# PSF Translational and Innovation Research Grant
# Grant Application Guidelines and Eligibility
## Submission Deadline: Friday, December 1, 2023

**Grant Description:** This grant intended to support novel translational innovative research (e.g., devices, diagnostics, technology, …) that accelerates discovery through FDA approval into clinical testing. The research must lead to improvements in commercial development, and the objectives of the project should include an outcome that will benefit patients and address unmet clinical needs. Evaluation of each proposal will be on the basis of scientific merit, potential health care impact and significance, experience of the investigators, the potential for commercialization or translation to patient care and for successfully obtaining further support. Projects must demonstrate stakeholder engagement and high translational potential for continued development to move into clinical practice, generate new clinical guidelines, or other applications via subsequent grant support, new company formation, licensing, not-for-profit partnering, and an evidence-base that changes practice or other channels. There is an emphasis on cross-disciplinary scientific research addressing the development of therapies, diagnostics, or devices applicable to plastic surgery. Proposals that include teams of investigators from different disciplines are encouraged. Projects should be milestone-driven and not discovery, hypothesis-based research. The grant is intended to support a viable commercial product, with plan for commercialization within three years. Projects with a clear path to market and go/no-go milestones will be favorably reviewed.

**Award Amount:** up to $50,000
**Project Duration:** Up to 12 months; No-cost extensions can be requested for up to a year (see "No-Cost Extensions" below.) Given that this mechanism is helping promote the multi-steps of innovation, the investigator may apply for up to two grants for the same project in different fiscal years. Specifically, projects may propose more than one year of milestones prior to anticipated translation, however, projects are funded for only one year at a time (i.e., you will need to reapply for a future year of funding). The second grant must clearly show how the 1st grant expedited the overall process of converting the research to a clinically relevant tool, device, medicine, etc.

**Earliest Start Date:** July 1, 2024
**Award Announcements:** June 2024

**Eligibility Requirements:**
*Applicants must…*

- be a MD, DO, or PhD
- hold a full-time clinical or research position where the research will be conducted.
    - will be conducted.
- be an Active, Candidate, International, or Associate member of ASPS or obtain sponsorship from an Active ASPS member at <u>your</u> institution
    - This is a requirement if you are currently in your training.
    - For multiple PIs, a sponsor is required for only the applying PI.
    - ASPS Associate Members may apply with identified ASPS Sponsor.

**Evaluation Criteria:** The PSF is dedicated to fostering the growth of research in Plastic Surgery. In order to ensure The PSF is successful in building a diverse, committed, inclusive, and self-sustaining plastic surgery research community, applications may also be evaluated on whether the PI is currently funded by The PSF, the PI has an open no cost extension by The PSF, or whether there are multiple grant submissions from the same lab at the same institution. The PI or their Sponsor's donation history to the PSF may also be considered in the review of the application.

## Preparing to Apply

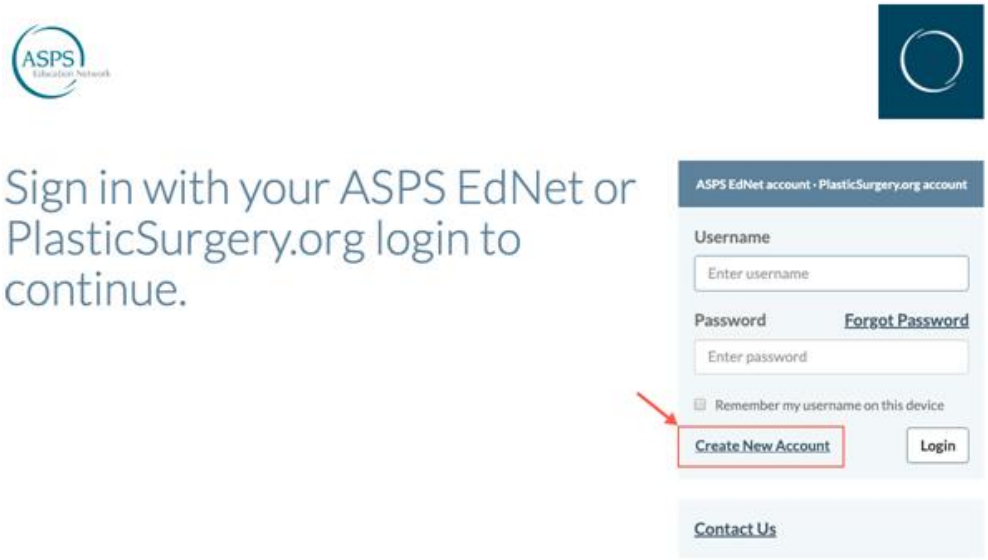
**Online Application:** All Applications must be submitted online through proposalCENTRAL. (proposalcentral.altum.com)

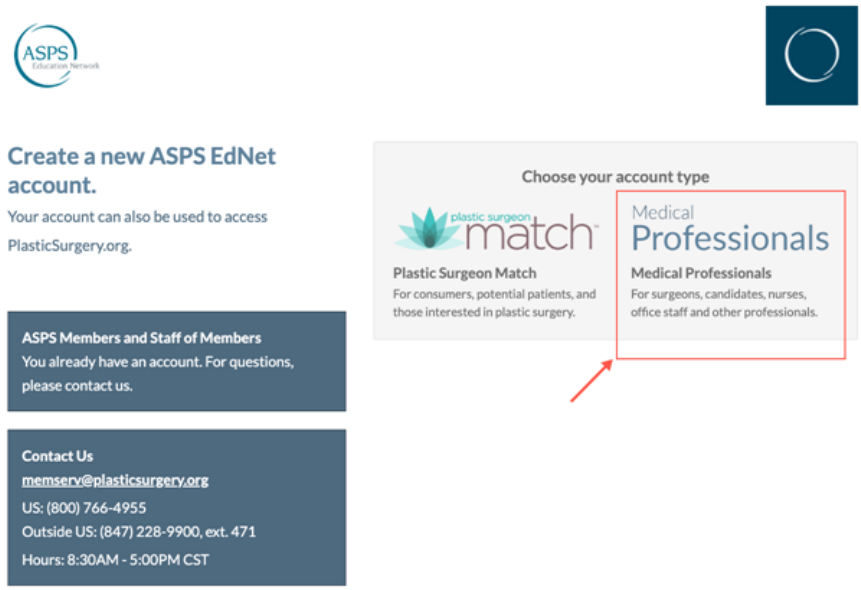
**Deadline: Grants must be submitted in proposalCENTRAL by 11:59 P.M. (EASTERN) on or before December 1, 2023. No late submissions will be accepted. Corrections of oversights/errors discovered after the deadline will not be allowed.**

**Multiple Submissions**: Projects will be awarded only one PSF grant per annual grant cycle. Applicants may submit more than one grant application ONLY if they are scientifically different, but only one research project may be funded.

**Grant Writing Module:** All applicants who have not been previously funded by The PSF must complete The PSF's Grant Writing Module. You can find the grant writing module on ASPS Ed Net at the following link: https://ednet.plasticsurgery.org/diweb/catalog/item?id=6158910

Applicants who have not previously logged in to plasticsurgery.org or ednet.plasticsurgery.org should click the 'Create New Account' link at the login screen to create a Medical Professionals account in order to gain access to the Grant Writing Module.



## Application Templates Check List with Page Limits

**Templates:** Bio-sketch, Other Support, Resources and Grant Writing Module Certificate templates are provided on the Research Plan & Other Attachments section in proposalCENTRAL.

**Formatting Requirements:**

- 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".
- Use at least one-half inch margins (top, bottom, left and right) for all pages, including continuation pages.

***Information Entered Directly into proposalCENTRAL.***

- ☐ **Project Summary** (2,500 characters max, including spaces)
- ☐ **Impact Statement** (800 characters max, including spaces)
- ☐ **Biography** (1,500 characters max, including spaces)
- ☐ **Budget**
- ☐ **Budget Justification**

***Templates to Download- Page Limits will be Strictly Enforced***

- ☐ **Other Support**
- ☐ **Resources**
- ☐ **Biosketch**
- ☐ **Grant Writing Module Certificate**

***Documents to Upload- Page Limits will be Strictly Enforced***

- ☐ **Signed Face Page**
- ☐ **Cover Letter for Resubmissions***
- ☐ **Biographical Sketch** _____ **5 PAGES each**
- ☐ **Other Support**
- ☐ **Resources**
- ☐ **Research Plan:** (Please upload each section separately)
  - ☐ **Specific Tasks/Milestones 1 PAGE**
  - ☐ **Science/Technology up to 6 PAGES** (Tables/ figures must be included within page limit)
  - ☐ **Human Subjects** _____ **1 PAGE**
  - ☐ **Vertebrate Animals** ___ **1 PAGE**
  - ☐ **Literature Cited** _____ **NO LIMIT**
  - ☐ **Leadership Plan** _____ **1/2 PAGE**
  - ☐ **Consortium/Contracts***
- ☐ **IRB /IACUC Approval Documentation*** (Each project must submit an IRB or APLAC approval number, or provide confirmation of non-human/non-animal subjects determination within 90 days of award notification)
- ☐ **Sponsor Letter***
- ☐ **Letters of Support***
- ☐ **Grant Writing Module***
- ☐ **Appendix*** _____ **NO LIMIT** (Upload any/all images as "Appendix" items)

** Submit if applicable – all other documentation is required*

## Key Personnel

***Documentation is required from the following personnel.***

| Personnel | Role Description | Biosketch | Other Support | Letters of Support | Sponsor Letter |
|---|---|---|---|---|---|
| **PI** (Applicant) | Applies for and writes the grant. Oversees and directs the research. | ✓ | ✓ | | |
| **Multiple-PI** "Co-PI" | Shares equal responsibility with PI. Does not need to be from the same institution as the PI. | ✓ | ✓ | ✓ | |
| **Co-Investigator** | Highly involved in the scientific development or execution of the project. Contributes measurable effort. Does not need to be from the same institution as the PI. | ✓ | ✓ | ✓ | |
| **Collaborator** | Moderately involved in the scientific development or execution of the project. Contributes measurable effort. Typically, from the same institution as the PI. | ✓ | | ✓ | |
| **Sponsor** | Required for non-ASPS applicants and those in training. Can also serve another role on the grant but is not required to. | ✓ | * | * | ✓ |
| **Other** | Research Fellows, Research Assistants, Technicians, Paid Consultants, etc. | * | * | * | |

**Not required unless also serving in another role, example: Co-Investigator or Collaborator, then follow those guidelines.*

## Application Templates

***Enter the following information directly into your application in proposalCENTRAL.***

**Project Summary:** This is the summary description of your research project. In language suitable for the public, please 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.

**Impact Statement:** In language suitable for the general public, describe the potential of real, clinical impact this research is likely to have on the practice of plastic surgery.

**Biography:** In language suitable for the general public, please include a professional biography.

**Budget:** *Complete all sections of the budget following these limitations:*

- Budgets can **NOT** include indirect costs, administrative costs, travel to meetings (presentations), and publications costs. Grant funds will not be used to purchase capital equipment* costing more than 5% of the total budget, intellectual property services, or food.
  - **Capital Equipment is defined as any asset having a useful life of more than one year. Examples include but are not limited to (laptop computers, iPads, software, cameras, cryogenic systems, incubators, dry boxes, cell counters, etc.)*
- Budgets **CAN** include salary for investigator and/or research personnel, travel (if project related) and supplies. *This can include virtual companies including subcontracts, contracts, and consultants. (Total costs for salary of investigators and consultants should not exceed $20,000.)*
- Budgets **CAN** include up to $10,000 for regulatory.

**Budget Justification (2 PAGES):** Please clarify and describe the purpose and need for each item listed on the Budget page, i.e., Personnel, Consultant Costs, Supplies, etc. Under Personnel, roles for each person should match what you have entered into proposalCENTRAL. If any additional monies will be used to support the project, please describe these, and provide proof of funding. The grant money should be used to distinctly complete at least one major milestone. For a study that requires more resources than this grant provides, please describe any institutional or other support you have.

***Upload these deliverables in the Research Plan & Other Attachments section of your application in proposalCENTRAL.***

**Face / Signature Page:** After completing your application in proposalCENTRAL, you will need to print your Face Page (Signature page) to obtain your institutional signatures. Once you obtain 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.

**Biographical Sketch (5 PAGES):** Submit an NIH bio-sketch for those directly involved with the project (see chart above for required personnel). 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 ____ (#)." List selected ongoing or completed (during the last three years) research projects. Begin with the projects that are most relevant to the research proposed in this application. Include the project number, dates, source of funds, project title, your role in the project and briefly indicate the overall goals of the research project. Do not list award amounts or percent effort in projects. See example provided within the proposalCENTRAL Templates page.

**Other Support:** Please provide information on all active or pending support from any source (see chart above for required personnel). Include the project number, dates, source of funds, project title, award amounts, percent of effort in months, and briefly indicate the overall goals of the research project. Indicate and explain any scientific or budgetary overlap between funding, and other overarching projects. For individuals with no active or pending support, please indicate NONE. See example provided within the proposalCENTRAL Templates page.

**Resources:** Limit the description of resources available to those identified on the form.

**Technical Discussion and R&D Plan –** *This section consists of **A & B** as outlined below must be a minimum of 5 pages and **no more than 7 pages**. The following page suggestions are provided to provide guidance on what is reasonable for each portion of this section.*

**Instructions:** Describe the innovation in sufficient technical depth for a knowledgeable reviewer to understand why it is innovative and how it can provide benefits in the target applications. Supplement this description with any necessary background information.

- Describe the key objectives to be accomplished during the Phase I research, including the questions that must be answered to determine the technical AND commercial feasibility of the proposed concept.
- Describe the critical technical milestones that must be met to get the product or service to market.
- Present an R&D plan, with timeline. What are the objectives, and what experiments, computations, etc. are planned to reach those objectives?

**A. Tasks and Milestones- *(1 page):*** Projects should be milestone-driven and not discovery, hypothesis-based research.

**B. Science/Technology –** ***(6 pages and includes all the items below)*** the following components are crucial. Start each section with the appropriate section heading - Significance, Innovation, Approach. Cite published experimental details in this section and provide the full reference in the Literature Cited section. Tables and Figures should be included within the text of this section.

1. **Significance –** ***(1/2 - 1 page)*** The novelty, uniqueness and impact of the opportunity presented by the proposal; opportunities that provide generalizable solutions to translational research problems are highly encouraged. An "elevator pitch" style is encouraged. Include size of the total market, addressable market, and potential future markets. Explain recent trends or changes in the market or field(s) and how the product is timely—build reviewer and investor excitement.

2. **Innovation –** ***(1/2 - 1 page)*** Describe the technical innovation. What is unique about the innovation. How will the innovation advance fields of study or clinical care? Include key technical challenges, risks in bringing the innovation to market, and plans for managing risks. Include previous publications related to the technology. **Innovation has**

**different stages. This mechanism is aimed toward the NIH definition of Phase 1 Applications** (defined as Feasibility and Proof of Concept):

*State the specific objectives of the Phase I research and development effort, including the technical questions you will try to answer to determine the Phase I feasibility of the proposed approach and the impact that the results of the proposed research will exert on the research field(s) involved. State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process, or service to ultimately be developed. Include milestones for each of the tasks as these will be used in the evaluation process.*

3. **Approach – *(3 pages)*** Focus is critically important. Include relevant preliminary data. Provide Tasks, not aims, and include rationale, overall strategy, methods, and analyses. Explain models used and pros and cons to the models. Include statistics and power analysis if relevant. Explain go and no-go decisions. Include pitfalls and approaches to solving problems. Explain what will be accomplished at the completion of the tasks and how it relates to the milestone(s).

4. **Intellectual Property – *(1/3 page)*** Describe the current state of intellectual property. Explain plans for creating new IP. What are your plans for protecting the IP. Explain competing IP and potential weaknesses in the IP portfolio. Who owns the IP, what is the current state of licensing? Who is assisting with IP creation and management? How will costs of IP be managed?

5. **Collaboration – *(1/3 page)*** Describe project team members or collaborators and explain their complementary skills and expertise. Has a company been formed, if so, describe the company structure and explain the history. What are the collaborators strengths? What are their unique strengths? Do collaborators have experience with commercialization-if so, how, and what?

6. **Translation** – (***no more than a 1/3 page)***
   Translational potential of the opportunity including strategy for launching the product and first sales. Will there be a direct sales force, distributor, or partnering, if relevant? If the product is ready for commercialization, how will marketing and advertising be handled? Who are the adopters of the technology and what pain point is this solving for them? What are the challenges in adoption? Who are the stakeholders? Who pays for the technology and what are their concerns, if relevant?

7. **Competitors – *(1/3 page)*** Describe the competition. How many competitors are there and what is their market share? What differentiates the technology from competitors? How will you obtain market share and protect market share? How do you expect the competitive landscape may change by the time the innovation enters the market.

8. **Regulatory Path – *(1/3 page)*** Explain the regulatory path, including timeline. Have competitors followed this path/timeline. Are clinical studies needed? Describe regulatory resources you expect will be needed to implement your approach.

9. **Follow-on funding – *(1/3 page)*** What are plans for project next steps and follow on funding? Will additional grants or private investment be sought? If so, please provide specifics? Has previous funding been secured—if so, please describe?

**Additional items:**

**A. Human Subjects (1 PAGE):** If applicable, briefly summarize 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. This includes Protection of Human Subjects, Inclusion of Women and Minorities, Inclusion of Children, and Targeted/Planned Enrollment Tables for Race and Ethnicity. Do not include the entire IRB application. In

addition, if available include copies of all Approval Letters from the appropriate IRB Board(s), including Biosafety and/or Radiation Safety (if applicable). Indicate N/A if you are not using Human Subjects within your research.

**B. Vertebrate Animals (1 PAGE):** If applicable, briefly summarize the use of animals in scientific research, including specific reference to adherence to accepted standards (e.g., NIH publication No. 86 23). In addition, if available upload the documentation of the project's review by the appropriate institutional committee, including Biosafety and/or Radiation Safety. Indicate N/A if you are not using Vertebrate Animals within your research.

**C. Literature Cited:** Please list all references in order of occurrence of their first mention in your proposal, in number or superscripted form.

**D. Leadership Plan (1/2 PAGE):** For applications proposing multiple PIs, or the Applicant has an ASPS Sponsor, a leadership plan is required. The governance and organizational 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. Indicate N/A if you are not required to submit a leadership plan.

**E. Consortium and Contractual Agreements:** If applicable, describe all research relationships required for this project carefully. Indicate N/A if this is not required.

**IRB/IACUC:** Institutional IRB/IACUC approval letters must be on file in The PSF Executive Offices within ninety (90) days of written notification of the Award. If the approval is not on file within the ninety (90) daytime frame, the Award will be rescinded by The PSF. All annual renewals of IRB/IACUC approvals must be sent to The PSF Executive Offices within thirty (30) days of receiving such renewal.

**Accurate Compliance with Institutional Regulatory, Financial and Conflict-of-Interest Policies**
Awardees must be in compliance with all aspects of their institutional policies for human subjects and animal research (IRB/APLAC) approvals; conflict-of-interest (COI) disclosure forms; and NIH/federal policies for allowable and allocable costs.

- For all research that involves live or dead vertebrate animals, an animal use protocol must be reviewed and approved by APLAC prior to commencement of the project.
- Project protocols should be submitted to their institutional IRB as soon as possible after notification of the grant award is received.
- Once investigators are notified of IRB approval/exemption, the study protocol ID# and date of approval/exemption should be submitted via proposalCENTRAL.
- If required, project investigators and their research staff must complete HIPAA (Health Insurance Portability and Accountability Act), and CITI (Collaborative Institutional Training Initiative) training.

**Sponsor Letter:** If the applicant is in training or is not an ASPS member, an original letter from your ASPS Sponsor must be submitted (see chart above for requirements). This letter must verify that the Applicant will be present and fully available to carry out the proposed work during the allotted time period. Applicants, for which this eligibility requirement is not met, will not have their application reviewed.

**Letters of Support:** All Co-PIs, Co-Investigators and Collaborators must submit an original Letter of Support for their involvement in your research project (see chart above for required personnel). Letters of Support are addressed to the applicant and should describe the Co-PI/Co-Investigator/Collaborator's credibility, intended contribution, role, commitment, and provide support for the work being proposed. If the Sponsor is also serving as a Co-PI, Co-Investigator or Collaborator, then the Sponsor Letter and Letter of Support can be combined. The Sponsor should indicate that they are also serving as a Co-PI, Co-Investigator or Collaborator for the project. A separate letter from each Co-PI/ Co-Investigator/ Collaborator is required.

## Additional Information

**Resubmissions: *IMPORTANT* IF YOU PREVIOUSLY SUBMITTED AN APPLICATION TO PSF FOR AN UNFUNDED PROJECT, AND THIS SUBMISSION IS A REVISION OF THAT PRIOR SUBMISSION, IT WILL BE TREATED AS A RESUBMISSION, EVEN IF IT WAS PREVIOUSLY SUBMITTED TO A DIFFERENT GRANT MECHANISM.** In addition to resubmitting all required application documents, 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 point-by-point discussion of the issues raised in your summary statement critiques. Please upload your Cover Letter in the Research Plan & Other Attachments section of your application in proposalCENTRAL. Note: Only those resubmitting a grant application must upload a Cover Letter.

**Reporting:** Progress reports (technical and financial) are due at six (6) months and twelve (12) months. For projects that continue to receive funding (from PSF or other sources), after the initial grant period, awardees will report annually to The PSF for up to seven years regarding how the initial funds translated to clinical outcomes. Details on reporting requirements will be sent to the PI once awarded.

**No-cost extensions:** Written requests for extensions must be received ninety (90) days before the expiration of the original grant period and are subject to approval by the Chair of The PSF Research Grants Committee. An approval of an extension DOES NOT include the award of additional funds. In addition, the Principal Investigator must provide The PSF with additional progress reports (technical and financial) six (6) months and twelve (12) months past the original project end date.

**Additional Funding:** The Principal Investigator may apply for additional funding. Those who want to expand upon their project at the end of the original time period will need to re-apply for additional funding. (See additional details in “Project Duration” section above.)

**Transferring Institutions:** This grant is NOT transferable to another individual within the Institution and NOT transferable to another institution OR to operating funds. If the Principal Investigator or Sponsor leaves the Institution, the Principal Investigator, Sponsor, and the Institution must notify The PSF within thirty (30) days and all unused funds MUST be returned.

**Budget Changes:** A certain degree of latitude to re-budget within and between budget categories to meet unanticipated needs is allowable. If expenses fall outside of the original approved budget categories by a degree of more than 10% of the total award, prior written approval will be required, along with a revised budget and a justification for why the changes are necessary to complete the project. In addition, inclusion of any budget category that was not included in the original approved budget must also be approved by The PSF. All reallocation requests are subject to the current grant guidelines and must be approved by The PSF.