# PSF/MTF Biologics Allograft Tissue Research Grant

**Grant Application Guidelines and Eligibility**

Submission Deadline: Monday, December 3rd, 2018

**Eligibility**

*Applicants must…*

- be a MD, DO, or PhD ☐
  - hold a full-time clinical or research position where the research will be conducted ☐
  - be an Active, Candidate or International member of ASPS or obtain sponsorship from an Active ASPS member at your institution ☐
    - This is a requirement if you are currently in your training
    - For multiple PIs, a sponsor is required for only the applying PI

**Grant Description:** The PSF and MTF Biologics offer research grants to investigators studying allograft tissue transplantation in plastic and reconstructive surgery. These grants are intended to provide support for research projects focused on biologic reconstruction with a strong clinical translation component that utilize dermal, adipose, placental or other allograft transplant technologies. Proposed studies should focus on novel research in the fields of tissue allograft transplantation, tissue allograft science, novel uses of allografts, allograft-derived materials and biologic reconstruction. However, proposals focusing solely on autologous grafts and synthetic applications that do not incorporate investigation of allograft use and/or grant proposals where the allograft is solely a scaffold for autograft materials (including cells) are beyond the scope of this award.

The PSF and MTF Biologics offer research grants for projects with a high likelihood of impact on scientific discipline and/or on patient care. Both clinical and basic science research projects will be considered for submission. Examples of clinical technologies of interest include but are not limited to the use of allograft biologics in breast reconstruction, wound healing, nose reshaping, soft tissue defect filling, allograft in fat transplantation and injection, use of allograft in tissue engineering or bioprinting, and other applications of allograft tissue in plastic and reconstructive surgery. Clinical evaluation of allograft tissues will also be considered for funding, following the same scientific topics and technologies previously described.

**IMPORTANT – Required:** Applicants **and their institutions** are required to sign the non-negotiable MTF/PSF Grant Intellectual Property Policy document at the time of their submission. **Documentation of the institution's agreement to the IP policy is a requirement for eligibility.**

Please direct any questions about the program or guidelines to Mary Ruth Arway, Research Grants Project Manager at rarway@plasticsurgery.org.

**Award Amount:** Up to $100,000
**Project Duration:** Up to 24 months
**Earliest Start Date:** July 1, 2019
**Award Announcements:** May 2019

**Reporting:** Progress reports (technical and financial) are due at six (6) months, twelve (12) months, eighteen (18) months, and final reports (technical and financial) are due at twenty-four (24) months. Details on reporting requirements will be sent to the PI once awarded.

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 the deadline. NO late submissions will be accepted. Corrections of oversights/errors discovered after the deadline will not be allowed.

**Multiple Submissions**: 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. For ASPS Members, log on to the PSEN Research and Technology page here: http://www.psenetwork.org/research-technology and complete the free Grant Writing module by Ergun Kocak, MD. For Non-ASPS Members click here: (http://www.thepsf.org/Documents/GrantWriting/story.html). Only the Applicant needs to complete the Module. Upon completion, print the final screen showing your completion of the Module or sign the "Grant Writing Module Certificate" found in proposalCENTRAL templates. Upload either document into the Research Plan & Other Attachments section in proposalCENTRAL.

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

## Deliverables Check List with Page Limits

*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)

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

- ☐ **Signed Face Page**
- ☐ **Cover Letter for Resubmissions***
- ☐ **Budget**
- ☐ **Budget Justification** _____ **2 PAGES**
- ☐ **Biographical Sketch** _____ **5 PAGES each**
- ☐ **Other Support**
- ☐ **Resources**
- ☐ **Research Plan:** (Please upload each section separately)

- ☐ **Specific Aims** _____ **1 PAGE**
- ☐ **Research Strategy** ___ **12 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*** (Required within 90 days of award notification)
☐ **Sponsor Letter***
☐ **Letters of Support***
☐ **PSF/MTF Biologics Grant Intellectual Property Policy**
☐ **Grant Writing Module***
☐ **Appendix*** _____ **NO LIMIT** (Upload any/all images as "Appendix" items)

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

**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.

## 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 isn't 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 Deliverables

***Enter** the following information directly into the Project Summary section of 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.

***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.

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

- Budgets can **NOT** include: indirect costs, administrative costs, travel, publications costs, or capital equipment*.
    - **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 **NOT** include salary support for PI, Co-PI, Co-Investigators, or Collaborators.
- Budgets **CAN** include salary for research assistants and lab technicians who are not also serving in other key personnel roles (see Key Personnel Chart above).

**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've entered into proposalCENTRAL. For a study that requires more resources than this grant provides, please describe any institutional or other support you have.

**Biographical Sketch (5 PAGES):** Submit an NIH biosketch 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.

*Upload each section of the Research Plan as* ***separate*** *PDFs into proposalCENTRAL even if you are indicating N/A.*

**Research Plan (A - G)**

**A. Specific Aims (1 PAGE):** 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, rationale and hypothesis.

**B. Research Strategy (12 PAGES):** Organize the Research Strategy in the specified order and using the instructions provided below. 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.

*Significance*

- Explain the importance of the problem or critical barrier to progress or gap in knowledge in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

*Innovation*

- Explain how the application challenges current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

*Approach*

- Discuss the PI's preliminary studies, data, and/or experience pertinent to this application.
- Provide detailed plans for analysis including statistical methods, control and experimental groups, as well as expected outcomes
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Please make sure to include discussion of your sample size justification and your power calculations, if applicable.
- Cite relevant publications to support your approach.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. Provide detailed pitfalls and alternative strategies. Consider and discuss how negative data will be used or interpreted.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- State how the findings from this study will inform the next stage of research.
- State expected outcomes and any potential limitations/obstacles to obtaining results.

**C. 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 Bio-Safety and/or Radiation Safety (if applicable). Indicate N/A if you are not using Human Subjects within your research.

**D. 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 Bio-Safety and/or Radiation Safety. Indicate N/A if you are not using Vertebrate Animals within your research.

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

**F. 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.

**G. 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) day time 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.

**Sponsor Letter:** If the applicant is in training, 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.

**PSF/MTF Biologics Grant Intellectual Property Policy:**

**Each application must be accompanied by the following commitment; under the signature of Principal Investigator and/or Sponsor and the responsible head of his/her institution, as follows:**

LIMITED RIGHT-OF-FIRST OFFER; ALLOGRAFT SUPPLY

In the event the investigator or his/her academic institution desires to commercialize any product or intellectual property resulting from work associated with the grant, then MTF Biologics shall have the following rights:

a) Notice. Both the investigator and his/her academic institution shall deliver written notice to MTF Biologics of such intended commercialization (the "Commercialization Notice"). Following delivery of the Commercialization Notice, the investigator and his/her academic institution shall from time to time respond to reasonable requests for information made by MTF Biologics with respect to the product, intellectual property or commercialization.
b) Right-of-First Offer. MTF Biologics may, within 30 days from the date of receipt of the Commercialization Notice, advise the investigator or his/her academic institution of its interest in commercializing such product or intellectual property. In the event MTF Biologics delivers advice to the investigator or his/her institution of its interest in commercializing such product or intellectual property, MTF Biologics and the investigator or his/her institution will thereafter endeavor to negotiate the identified relationship in good faith, and will use all reasonable efforts to agree upon terms, conditions and other provisions within 60 days of MTF Biologics' advice as aforesaid. If no such agreement is reached within such period, neither the investigator nor his/her institution will be constrained in the commercialization of such product or intellectual property, except as set forth in Paragraph (c), and except that an agreement with any other party with respect to such commercialization will not be on terms less favorable to the investigator or his/her institution than those last proposed by MTF Biologics.
c) Allograft Supply. With limiting the rights of MTF Biologics under Paragraph (b), the parties acknowledge and agree that MTF Biologics will in all events be the sole supplier of allograft materials to support the commercialization of any product or intellectual property covered by a Commercialization Notice, upon MTF

Biologics' customary terms and conditions attendant to such allograft supply. In the event of any Commercialization Notice, MTF Biologics and the investigator or his/her institution will thereafter document such supply arrangement in good faith as expeditiously as practicable after the Commercialization Notice. Notwithstanding any other provision in this Paragraph (c), MTF Biologics may at any time deliver notice to the investigator or his/her institution that it does not elect to supply allograft materials in connection with such commercialization, in which case MTF Biologics will not be obligated to supply allograft materials and neither the investigator nor his/her institution will be constrained in arranging for an alternative supply.

## Special Situations and Agreements

**Resubmissions:** 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.

**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.

**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 your expenses fall outside of your original approved budget categories by a degree of more than 10% of your total award, prior written approval will be required, along with a revised budget and a justification for why the changes are necessary to complete your 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.