



# INNOVATION IN ALLOGRAFTS TRANSLATION RESEARCH GRANT

## 2024 APPLICATION INSTRUCTIONS

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### **POLICIES**

All policies pertaining to and governing this grant program are contained in the document titled “MTF Biologics Grant Program – 2024 Administrative Policies and Procedures”. This document is available on the MTF Biologics website and from the MTF Biologics Grants Office. It is the responsibility of the grant applicant and their institutions to understand all applicable policies associated with their grant applications.

All MTF Grant policies are final and non-negotiable. Any requests for alterations, omissions or other redlining of the MTF Grant Policies will be denied and the grant application will not be considered for funding.

All sections of the application must be completed. All signatures are required to process the application.

Any grant proposals submitted without the required signatures in any section will not be reviewed for funding.

### **Page Layout and Formatting**

- The use of the provided form is required.
- The **written research plan must not exceed the page limitation of 8 pages.**
- Proposals must be typed in a font at least 10 point in size, NO LESS.
- Margins must be no less than 0.5” on both the left and right sides, 1” inch at the top and bottom of each page.
- Ensure that all Figures and Tables are legible.
- Do not include multiple page images on one page.

### **SUBMISSION INSTRUCTIONS**

Applications must be submitted electronically via the MTF Biologics Grants web portal. A single PDF file of the entire application package is required to be uploaded to the grant portal to submit the application.

### **INSTRUCTIONS FOR COMPLETING APPLICATION FORMS**

All boxes must be completed or marked N/A.

MTF Biologics Grant Application Checklist

This checklist is provided as a reference to ensure that all sections of the application are complete prior to submission of the application. The checklist does not need to be submitted with the application.

The following are specific instructions for some key items.

- A. Application Face Page and Information Page (Pages 1-4)

1. Page 1 is the cover sheet for the entire application. Pages 2 – 4 require information about the Department Chair, Institution’s Financial Officer, other investigators and miscellaneous grant information.
  - Where indicated at the top of the page, check off whether this is a resubmission application.
2. For investigator and institution information, enter specific titles, departments, and contact, where indicated.
3. NPI numbers are required for the Principal Investigator (Box 5c) and Institution (Box 6c), if applicable.
4. For more than two co-Investigators, enter their information on Continuation Pages.
5. Enter specific payment instructions (to be used if the grant is funded) in Box 11c.
6. Enter the requested information regarding IRB and IACUC approvals in boxes 15 and 16. If approvals are pending, state PENDING in the place of the approval number Assurance of final IRB and IACUC approvals will be required prior to disbursement of any grant funds.
7. Enter the Principal Investigator’s name in the header where indicated.

B. MTF Biologics 2024 Grant Application – Signature Acknowledgments (Pages 5-6):

1. Use black or blue ink for all signatures. Verifiable Electronic signatures are also acceptable.
2. Signatures are required from the following:
  - i. Principal Investigator (i.e., Applicant)
  - ii. Department Chair
  - iii. an Institutional Officer (or designee)
  - iv. the Institution’s Financial Officer (or designee)
  - v. any co-Investigators associated with project.

C. MTF Biologics Policy on Grant Intellectual Property (Page 7):

Please include this policy page in the submitted proposal without any modifications.

D. Keyword List (Page 8):

1. This list will be used to assign your grant proposal to the appropriate reviewers.
2. Rank three of the provided keywords in order of relevance to the proposed research project, with 1 being the most relevant. If a selection of “Other” is made, type in one appropriate keyword.

E. Abstract of Research Plan (Page 9)

1. Provide a **1 page abstract** with up to 3 underlined phrases to highlight the project. The abstract should be a stand-alone item that provides some background and rationale to the research being proposed; hypothesis; specific aims; experimental design; and potential outcomes.
2. Do not exceed the space provided on the Template.

F. Innovation Statement (Page 10):

Provide a 1 page statement on the innovative and translational aspects of your grant application. For example:

1. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
2. 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.
3. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
4. Describe the novel use of allograft or allograft-derived tissues and/or technologies, and explain the rationale on why such use would lead to improved patient care.
5. State the translatability of the proposed research.

G. Personnel & Facilities Disclosure Form (Page 11):

1. Key Personnel: List key personnel associated with the project. Include their organization and expected role on the project. Provide details on the Budget Justification page.
2. Performance Site(s): List name and location of site(s) where the work will be performed. Provide details on the Facilities form.

H. Budget and Justification (Pages 12-14):

1. All budget requests must follow the Financial Policies and Budget Policies published in the **MTF Biologics Grant Program – 2024; Administrative Policies and Procedures**.
2. Deviations from the published policies must be stated on the Budget Justification Form.

1. Salary

- a. Enter the name, percent of time on project and salary requested. Fringe benefits are allowable in the MTF Biologics Grant awards. Suggested total salary varies by grant type as follows:

- i. Extramural: 35% of total grant request
- ii. Clinical: 50% of total grant request
- iii. Career: 50% of total grant request

b. The indirect expenses rate is capped at 20% of requested total direct costs.

- 2. Permanent equipment: Any requests for major piece of equipment or apparatus costing more than \$1,000.00 should be itemized, and justifications made.
- 3. Consumable supplies: Glassware, chemicals, supplies and all expendable materials obtained from the stockroom of the institution may be grouped in this category under appropriate subheading.
- 4. Other Expenses: list other expenses required for completion of the project. Justify any significant expenditures.

ii. Justifications (page 14)

- 1. Include justifications for any salary requests above the suggested salary caps.
- 2. Include justifications for any permanent equipment
- 3. Include any other justifications which you feel will aid the reviewers in understanding the specific requests

I. Research Disclosure Form (Page 15)

- 1. List Prior MTF Biologics Grant Support
- 2. List research funding relevant to this project for the past five years.
- 3. List funding received for other research projects the last five years, including your own institution.
- 4. List current funding, identifying potential overlap and no potential overlap of projects. On projects with funding of \$50,000 or more with potential overlap, list the aims of that project.
- 5. Indicate if the candidate has/had NIH funding. For Junior Investigator and Career Development Grant applications, the candidate is eligible for MTF Biologics funding if the grant was a NIH training grant. But, the candidate is not eligible for a Junior Investigator or Career Development grant if he/she was the principal investigator on a NIH RO1 grant or its equivalent.

J. Biosketch – Principal Investigator (Pages 16-18)

- 1. Biographical sketches must be submitted for the Principal Investigator. The Biosketch must not exceed space provided (three pages) for each person. Limit the information to experience relevant to the project.

K. Biosketch(es) – Co-Investigator(s) (if applicable) (Page 19-21)

1. Biographical sketches must be submitted for all co-investigators. The Biosketch must not exceed space provided (three pages) for each person. Limit the information to experience relevant to the project .

L. Research Plan & Support Documents (Page 22)

1. Complete this section on the continuation pages provided, giving details following the outline below.
2. Research Plan: The research plan (items i-v below) for the total proposal must not exceed eight (8) pages. For resubmission applications, address prior year's comments in bold type, or alternatively, one additional page may be used address the prior year's comments.

- i. Specific Aims - Provide testable hypotheses and concise statement of the aims of the proposed research.
- ii. Background, Significance and Rationale - Summarize important results to date obtained by others on the problem, citing publications. Explain why the results of the proposed work may be important.

The rationale for the proposed research plan should be based on: 1) unmet scientific or clinical/medical need(s); 2) plausible biological mechanism(s); 3) compelling preliminary data; 4) compelling preclinical (in vivo, ex vivo and/or in vitro) data for clinical proposals; and 5) preliminary pre-clinical and/or clinical data if available.

- iii. Preliminary Studies/Progress Report - Describe briefly any work you have done that is particularly pertinent. On projects where human subjects are placed at some risk, where animals are used for experimentation or where there is a laboratory methodology with which the applying institution has not had well documented experience, the investigator is encouraged to submit a pilot study.
- iv. Translation: The translatability of the proposed research topic must be described, including at least statements regarding how the proposed funding will advance the technology towards clinical use, what the expected timeline for translation is and any potential pitfalls.
- v. Research Design and Method - Give details of your research plan, including how the results will be analyzed. For each specific aim mentioned in the "Specific Aims" Section, show how your plan is expected to fulfill the aim. Include your specific plans for what you hope to accomplish within defined timeframes; e.g., 6 months, 9 months, 12 months, 18 months, 24 months and 36 months, etc. Include method of statistical analysis, if relevant. Power studies justifying sample sizes, and therefore cost of the grant, would be strongly encouraged.

Secondary Aims: Issues of study feasibility and refinement of study procedures may be addressed as secondary aims, but not as the primary aim. Examples of such secondary aims include:

- Determining the optimal measure (endpoint), its variability, and/or the optimal timing of outcome evaluations in the context of the intervention
- Collecting information on the utility of questionnaires, rating scales, or biomarkers
- Developing and refining data collection procedures
- Optimizing the administration of the study intervention
- Developing and refining standardized methods of assessing outcome
- Optimizing methods for identifying, recruiting, and retaining study participants
- Creating clinical trial infrastructure

Multiple Questions: There may be multiple questions remaining to be answered before larger, more robust studies can be designed and conducted. The proposed study is not required to address all potential questions but the applicant should clearly state what the long-term development plan to answer the questions would be.

### 3. Support Documents

- i. Human Subjects – Attach a Human IRB statement, if applicable. IRB approval is required for invasive procedures. (Limit to 1 page maximum.)
- ii. Vertebrate Animals – Attach a Vertebrate Animal IACUC approval, if applicable. (Limit to 1 page maximum.)
- iii. Cited Literature – List material referenced in application (Limit to 2 pages maximum.)

### M. Letters of Recommendation

1. The following letters of recommendation/support are required for all applicants:
  - i. Chair of your Department.
  - ii. Your Institution, acknowledging support for your program and availability of facilities
2. Additional letters of recommendation are required for all applicants for the Dr. William F. Enneking of Career Development Grant:
  - i. MTF Biologics Academic Member Sponsor.
  - ii. Present Director of Research

### N. Career Goals (Dr. William F. Enneking Career Development Award Applications only)

1. Career Goals - Provide a statement on career goals, including a summary of past accomplishments in research, citing future research goals with potential for future NIH funding.
2. Time Allocated to Research Project - Provide statement on time allocated to the project, including the percent of time and the use of time during the thirty-six month period.

3. Relevance of the Project to the Mission of the Musculoskeletal Transplant Foundation.

MTF's Mission Statement is: The Musculoskeletal Transplant Foundation is a non-profit organization dedicated to providing quality tissue, services and devices to meet the needs of donors, their families, recipients, and the surgical community.

<b>For inquiries regarding the grant application process</b>	<b>For inquiries of a confidential or scientific nature</b>
Ms. Christine Jenkins Grant Administrator 125 May Street Edison, NJ 07728 (732) 661-2159 <a href="mailto:christine_jenkins@mtf.org">christine_jenkins@mtf.org</a>	Jeffrey Cartmell, Ph.D. Sr. Director, Intellectual Property & Grants 125 May Street Edison, NJ 07728 (732) 661-2151 <a href="mailto:jeffrey_cartmell@mtf.org">jeffrey_cartmell@mtf.org</a>