



MTF BIOLOGICS RESEARCH GRANT

APPLICATION INSTRUCTIONS

POLICIES

All policies pertaining to and governing this grant program are contained in the document titled “MTF Biologics Grant Program – 2018 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 grant policies are non-negotiable.

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 forms 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 email or by sending a CD/USB Drive to the MTF Biologics Grants Office. A single PDF file of the entire application package is required. High quality image files can be sent if the applicant feels that such images do not reproduce well in the PDF files. If the application package is larger than 10MB, send the application on appropriate electronic media to the MTF Biologics Grants Office.

Submission Instructions:

Format: **Applications must be submitted electronically as a PDF file.**

Via Email: Dr. Jeffrey Cartmell at jeffrey_cartmell@mtf.org

Via CD: Dr. Jeffrey Cartmell, MTF Biologics, 125 May Street, Edison, NJ 08837

Upon receipt, applications will be evaluated for completeness by the MTF Biologics Grants Office. Applications that are incomplete, do not adhere to the required formatting, are missing signatures, or otherwise deviate from stated MTF Biologics Grant policies will not be reviewed.

INSTRUCTIONS FOR COMPLETING APPLICATION FORMS

All boxes must be completed or marked N/A.

The following are specific instructions for some key items.

A. Application Face Page and Information Page (Pages 1-2)

1. Page 1 is the cover sheet for the entire application. Page 2 requires information about the Institution's Financial Officer, other investigators and miscellaneous grant information.
2. Where indicated at the top of the page, check off the following classification information:
 - i. Category for the research application: Clinical Science, Extramural Research, or Career Development.
 - ii. Investigator Type: Junior or Established (Career Development applicants should check N/A)
 - iii. Whether this is a resubmission application.
3. For investigator and institution information, enter specific titles, departments, and contact, where indicated.
4. NPI numbers are required for the Principal Investigator (Box 5c) and Institution (Box 6c), if applicable.
5. For more than two co-Investigators, enter their information on Continuation Pages.
6. Use black ink for all signatures. Signatures are required from the Department Chairman (Box 7), Applicant (Box 9b), official authorized to sign for the Institution (Box 10b), the Institution's Financial Officer (Box 11b), and other investigators associated with project (Boxes 12i, 13i and any continuation pages).
7. Enter specific payment instructions (to be used if the grant is funded) in Box 11c.
8. 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.
9. Enter the Principal Investigator's name in the header on Page 2 9and any subsequent pages).

B. MTF Biologics Policy on Grant Intellectual Property (Page 3)

1. **Edits to this policy will not be entertained or accepted.**
2. Both the Principal Investigator and an Authorized Institutional Representative must sign this policy where indicated.

C. Keyword List (Page 4):

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.

D. Abstract of Research Plan (Page 5)

1. Provide a **1 page abstract** with 5 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.

E. Performance Sites and Key Personnel (Page 6):

1. Performance Site(s): List name and location of site(s) where the work will be performed. Provide details on Page 10 under Facilities.
2. 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.

F. Table of Contents (Page 7):

1. Complete the Table of Contents. Reference the page numbers of your application.

G. Budget Form and Justification (Pages 8-9):

1. All budget requests must follow the Financial Policies and Budget Policies published in the **MTF Biologics Grant Program – 2018; Administrative Policies and Procedures**.
2. Requested deviations from the published policies must be stated on the Budget Justification Form.

i. Budget Form (Page 8)

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 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 9)

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

H. Facilities and Research Disclosure Form (Page 10)

1. List facilities available at your institution. Include laboratory space and major equipment available for use with this investigation.
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 RO 1 grant or its equivalent.

I. Biosketch – Principal Investigator (Pages 11-12)

1. Biographical sketches must be submitted for the Principal Investigator. The Biosketch must not exceed two pages for each person. Limit the information to experience relevant to the project.

J. Biosketch(es) – Co-Investigator (if applicable)

1. Biographical sketches must be submitted for all co-investigators. They may not exceed two pages for each person. Limit the information to experience relevant to the project.

K. Research Plan & Support Documents

1. Complete this section on the continuation pages provided, giving details following the outline below.
2. Research Plan: The research plan (items i-iv 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. 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. Literature Cited - List material referenced in application (Limit to 2 pages maximum.)

L. 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. The additional letters of recommendation are required for all applicants for the W.F. Enneking of Career Development Grant:
 - i. MTF Biologics Academic Member Sponsor.
 - ii. Present Director of Research

M. Career Goals (W.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.