

## **MTF EXTRAMURAL GRANT PROGRAM: 2016**

### **ADMINISTRATIVE POLICIES AND PROCEDURES Grant Categories, Eligibilities, Research Objectives & Policies**

The Musculoskeletal Transplant Foundation (MTF) 2016 extramural research program reflects the Foundations' interests and objectives involving allograft transplantation and biologic reconstruction. MTF will consider both clinical and basic science research proposals for the 2016 research grant program. There are three (3) types of MTF-administered grants:

1. **Established Investigator Award:** The objective of the proposed research is to advance allografts, the science of transplantation and the biological reconstruction of musculoskeletal tissues. MTF will consider both clinical and basic science research proposals for the 2016 research grant program. The applicant can be from any accredited institution or university.

An Established Investigator is one who, as a PI, has received prior research funding from a federal agency or a foundation, and has published in a peer reviewed journal as the Principal Investigator.

Grants will be offered at up to \$100,000.00 for each year (inclusive of indirect costs and salaries and wages) and a maximum of 3 years; indirect costs are limited to 20%; and salary costs should be no more than 35% unless fully justified. Increased levels of salary support (above the 35% limit) for *Clinical research proposals* will be considered if appropriately justified in the application.

2. **Junior Investigator Award:** The objective of the proposed research is to advance allografts, the science of transplantation and the biological reconstruction of musculoskeletal tissues. MTF will consider both clinical and basic science research proposals for the 2016 research grant program. The applicant can be from any accredited institution or university.

A Junior Investigator is one who must have completed either their post-doctoral or residency training (for Ph.D.'s and M.D.'s, respectively). Additionally, the applicant must not have previously received a grant as a Principal Investigator (PI) from a Federal Agency or a private Foundation.

Grants will be offered at up to \$100,000.00 (inclusive of indirect costs and salaries and wages) and for up to one year; indirect costs are limited to 20%; and salary costs should be no more than 35% unless fully justified. Increased levels of salary support (above the 35% limit) for *Clinical research proposals* will be considered if appropriately justified in the application.

3. **W.F. Enneking Career Development Award:** The MTF W.F. Enneking Career Development Award is intended to foster the development of outstanding orthopaedic clinicians and enable them to expand their potential to make significant research

contributions to the field of orthopaedics. It is expected that following this experience, the candidate will be able to pursue an independent and productive career in orthopaedic research and clinical medicine. MTF will provide a stipend of \$100,000 per year for up to three years. Both clinical and basic science projects will be considered for funding.

For the W.F. Enneking Career Award, the applicant must be a post-resident M.D. or D.O. from a MTF Academic Member institution. The institution must have a well-established orthopaedic research and clinical career development program and qualified faculty in clinical and basic research to serve as mentors.

**General Policies for All Grant Categories**

**1. Deadline Date for all Submissions: September 1, 2016.**

All applications must be received by the MTF Grants Office by September 1, 2016. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to the MTF Grants Office. If errors must be corrected on a submitted application, a changed/corrected application must be submitted to MTF Grants office on or before the application due date. If a Changed/Corrected application is submitted after the deadline, the application will be considered late, and at the discretion of the MTF Grants office the original application may be utilized for peer review.

Applicants are encouraged to consult with MTF Grants Office staff as they develop their plans for submitting an application are being developed. Early contact will provide an opportunity to clarify MTF’s policies and guidelines as well as to discuss how to develop an appropriate research plan, project timeline and milestone plan, which is subject to peer review.

**2. Award Information**

Funding Instrument	Grant: A support mechanism providing money to an eligible entity to carry out an approved project or activity.
Application Types Allowed	<ul style="list-style-type: none"> <li>• New Applications</li> <li>• Resubmission Applications (An application can be resubmitted twice)</li> </ul>
Funds Availability and Anticipated Number of Awards	The number of awards is contingent upon MTF appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	<p><u>Established Investigator</u>: Total awards are limited to \$300,000 over the three-year period, with yearly awards limited to \$100,000.</p> <p><u>Junior Investigator</u>: Total awards are limited to \$100,000 over the one-</p>

	<p>year period</p> <p><u>Career Development</u>: Total awards are limited to \$300,000 over the three-year period, with yearly awards limited to \$100,000.</p> <p>Indirect costs are limited to 20% of the total award.</p> <p>Salary support is limited to 35% of the total award for Basic Science Applications. Increased levels of salary support (above the 35% limit) for <i>Clinical research proposals</i> will be considered if appropriately justified in the application.</p>
Award Project Period	<p>The scope of the proposed project should determine the project period. The maximum project period is three years for the Experienced Investigator and Career Development Awards. The maximum project period is one year for the Junior Investigator Award. Two six-month no-cost extensions at the end of the grant period may be granted if justified at that time.</p>
Sunshine Reporting	<p>MTF reports all applicable grant awards to the appropriate Sunshine databases.</p>

### 3. Eligibility Information

- a. Eligible Institutions:
  - Public/State Controlled Institutions of Higher Education
  - Private Institutions of Higher Education
  - Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply, however all award funds will be disbursed to non-domestic institutions in U.S. Dollars. Such institutions will be responsible for conversion to local currency.
  
- b. Investigators:
  - Established Investigator: An Established Investigator is one who, as a PI, has received prior research funding from a federal agency or a foundation, and has published in a peer reviewed journal as the Principal Investigator. All proposals from accredited institutions or agencies will be considered.
  
  - Junior Investigator: A Junior Investigator is one who must have completed either their post-doctoral or residency training (for Ph.D.'s and M.D.'s, respectively). Additionally, the applicant must not have previously received a grant as a Principal Investigator (PI) from a Federal Agency or a private Foundation
  
  - WF Enneking Career Development Award: The applicant must be a post-resident M.D. or D.O. from a MTF Academic Member institution. The institution must have a well-established orthopaedic research and clinical career development program and

qualified faculty in clinical and basic research to serve as mentors (as detailed in the Career Development Award Application Instructions).

#### 4. Application Procedures

It is critical that applicants read and follow all application instructions in the Administrative Policies and Procedures as well as any program-specific instructions noted in RFPs or individual applications (if applicable). When the program- or application-specific instructions deviate from those in the Administrative Policies and Procedures, follow the program- or application -specific instructions. Conformance to all requirements is required and enforced. Applications that do not comply with these instructions may be delayed or not accepted for review.

Obtain a specific application form for each category. The total written proposal including required forms should not exceed 20 pages. Applications can be resubmitted two times for consideration. For resubmission of proposals, at least one additional page will be required solely to address the prior year's critiques. Do not use an Appendix to circumvent page limits.

Application forms may be obtained from the MTF website: [www.mtf.org](http://www.mtf.org) at the following URL: [http://www.mtf.org/research\\_grant\\_programs.html](http://www.mtf.org/research_grant_programs.html).

Additional application forms can be obtained by contacting:

The Musculoskeletal Transplant Foundation  
Attn: Ms. Ava DeGrose, Grant Administrator  
1232 Mid-Valley Drive  
Jessup, PA 18434  
(570) 496-3436  
[ava\\_degrose@mtf.org](mailto:ava_degrose@mtf.org)

#### Items Required:

- Completed *Request For Grants Application Form*
- 1 Page *Abstract* including both Specific Aims and with five (5) key phrases or words underlined
- For resubmissions only, at least 1 additional page specifically addressing critiques on the prior submission (Note: this does not count towards the 20 page limit.)
- Detailed Research Proposal. PI's name at the top of each page is recommended
- Institution IRB or IACUC Approval, if applicable
- *Biographical Sketches* for all Project Personnel
- Completed *Budget Form* and attached Budget Justification Sheet, if applicable
- *Facilities and Research Disclosure Statement*

**Proposals must be typed in a font at least 12 cpi or 10 point in size, NO LESS .** Margins should be no less than 1/2 inch on both the left and right sides, 1 inch at the top and bottom of each page. Total submission including all required forms and written proposal must not exceed 20 pages. However, as indicated above, at least one additional page is required on resubmissions to address prior year's critiques.

If original photographs are submitted, please be sure to include quality copies, to support statements being made. For electronic submissions, please ensure that all Figures and tables are legible.

Applications are preferably submitted electronically via email or by sending a CD to the MTF Grants Office. A single PDF file of the entire application package is preferred. High quality image files can be sent if the applicant feels that such images do not reproduce well in the PDF files. Such file shall be sent as TIFF or JPEG files. The MTF email servers limit incoming file sizes to 10 Mbytes. Therefore, if the application package is larger than 10MB, it is recommended to send the application on appropriate electronic media to the MTF Grants Office.

Paper applications will be accepted, but they will be scanned in as PDF files for the peer review process. MTF cannot guarantee the quality of such scans, therefore electronic submission is recommended.

Upon receipt, applications will be evaluated for completeness by the MTF Grants Office. Applications that are incomplete will not be reviewed.

### **Submission Instructions:**

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|---|---|
| <b>Format:</b>                            | For 2016, applications can be submitted either electronically as a PDF file or via hardcopy.                                      |
| <b>Via Email:</b>                         | Ms. Ava DeGrose at <a href="mailto:ava_degrose@mtf.org">ava_degrose@mtf.org</a>   |
| <b>Via Hardcopy:</b><br>(or CD/USB Drive) | The Musculoskeletal Transplant Foundation<br>Grants Program<br>1232 Mid-Valley Drive<br>Jessup, PA 18434<br>Attn: Ms. Ava DeGrose |

## **5. Research Plan**

All applications must contain a detailed research plan. The decision on what specific items are required for inclusion in each research plan is left to the discretion of each principal investigator. However, investigators are encouraged to review the following points when devising their research plans.

- **Rationale:** 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.
- **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.

## 6. Application Reviews and Notification of Awards

Each proposal received by MTF will be held in confidence by the administration and by all selected reviewers of proposals.

Each proposal will be reviewed by three scientists and/or clinicians depending on the topic of research. The reviewers are selected based on their topic(s) of expertise and are anonymous to each other. All proposals for clinical research will be reviewed only by clinicians.

Each proposal is numerically evaluated for A) need or potential impact of the study as related to tissue transplant science, allografts and/or surgical reconstruction of tissues; B) scientific quality of the proposal (reasoning, methods, experimental design, etc.); and C) the ability to complete the investigation in a timely manner (includes appropriate equipment, facilities, preliminary work, or mastery of techniques, etc.).

All proposals are numerically ranked and reviewed by the MTF Board of Directors' Research Committee. The scores and reviewer comments are used to form recommendations to the MTF Board of Directors. The MTF Board of Directors review and select the final proposals meriting award.

The Musculoskeletal Transplant Foundation will notify each applicant by email or letter no later than February, 2017. All PIs will receive a numerical evaluation plus the reviewers' critiques concerning strengths and weaknesses of the proposal.

## 7. Funding Information

The period of funding is for up to three years, depending upon award type, starting February, 2017.

All recipients of MTF Grant awards will receive 90% of their support made in three payments during the calendar year. If subsequent years are involved, each funded year will begin in February. **A final 10% payment (for each year) will be made upon receipt of a research progress report, which is due in January 2018. A detailed financial report showing the use of all funds awarded is also required as part of the research report made to MTF.** The progress and accounting reports need to be received by MTF prior to the release of the final 10% of funding for each year, and the beginning of the next funded year.

## 8. General Financial Policies / Expectation of Institutional Responsibilities:

Grantee institution is expected to provide all necessary, basic facilities and services. These include the facilities and services that normally could be expected to exist in any institution qualified to undertake orthopaedic research.

In particular, it is expected that the grantee institution will provide, whether from its own funds or from grant funds other than those of the Foundation, the following, unless otherwise specifically agreed upon:

- Laboratory space
- Maintenance service, including maintenance, supplies and service contracts
- Telephone services
- Library service, including subscriptions to periodicals and the purchase of books
- Laboratory furniture
- Salary of other investigators and of secretarial personnel
- Worker's compensation, public liability or other hazard and special insurance
- Office equipment
- Employee group life, disability, medical expense or hospitalization insurance
- Lantern slides, color plates, etc.
- Hospital bed expense, nursing or related services, even though used for research studies.
- Indirect Costs
- Tuition expenses of personnel on grant.

As a matter of policy, Foundation funds may not be used for remodeling or building construction costs.

Equipment purchased under Foundation grants become the property of the institution, unless otherwise specified by the Foundation before termination of the grant or its extensions.

## **9. Budget Policies**

If a budget approved by MTF's Board of Directors is less than that requested, new budget forms will be sent to grantee when notification of award is made. These forms must be completed, signed by the principal investigator and financial officer of the institution, and returned to the Foundation for approval, within thirty (30) days after notification.

Separate accounts must be maintained for each grant. These accounts, with substantiating invoices and payrolls, must be available at all times to representatives of MTF.

Grantee must request permission and receive written approval from the Foundation prior to making any changes to approved budget and moving funds between budget categories.

Grantee may terminate a grant prior to normal expiration date by notifying the Foundation in writing and stating the reasons for termination. Unexpended funds must be returned to the Foundation within sixty (60) days, together with a final report of expenditures and project status. The Foundation reserves the right to terminate grants at any time upon three months written notice.

At expiration of the grant period, any unexpended balance of \$100.00 or more must be refunded to the Foundation within sixty (60) days together with the report of expenditures and accompanying documentation, properly submitted.

If grantee has not completed the project prior to expiration, and for just reason, grantee may submit to MTF thirty days prior to expiration, a request for a six month no-cost extension, stating reason

and requested period of extension. Two 6-month extensions may be requested in writing. If the grant project is not completed upon the agreed deadline, the PI will lose the remaining 10% of the granted funds. **Any unexpended funds in excess of \$100.00 at the completion of the grant must be returned to MTF.** Unusual circumstances will be considered in the extension requests.

Miscellaneous expenses:

- Retirement plan and Federal Insurance Compensation Act employer contributions may be charged to grants, when such contributions are the normal practice of the institution. The percentage of such costs charged on behalf of a given individual must be calculated based on the percentage of that individual's salary charged to the grant. These expenditures must be shown in this category for approval.
- Up to 200 reprints, without covers, of any paper carrying the credit line "Aided by a Grant from the Musculoskeletal Transplant Foundation" may be charged against the grant if the candidate so desires.
- Reasonable travel funds can be charged against the grant.

## **10. Progress Reports & Final Reports**

Both Financial and Scientific Progress Reports are required for MTF Grants. The Principal Investigator is responsible for submitting the scientific progress report due in January of each granted year, or the final report at that time if work has been completed. A financial report prepared and signed by the Institution's designated Financial Office is also required at that time.

Reports of expenditures must be prepared every twelve months, be signed by the responsible financial officer, and submitted to the Foundation for approval with accompanying documents. Expenses must be submitted by category, i.e., Salary and Wages, Equipment, Supplies, Animals, Other. Fifty percent (50%) of Foundation funds must be expensed before the next grant payment will be sent.

*The final 10% of any grant award whose Principal Investigator does not submit both a scientific report and a financial expenditure sheet for the entire grant period will be withheld until both documents are on file at the MTF Research office. The Principal Investigator is responsible for acquiring the financial report from the appropriate financial agent at his or her institution.*

The Principal Investigator may request in writing two 6-month no-cost extensions if the project is not completed by the end of the third year. If the two required reports are not submitted after the agreed to reporting date, the PI will lose the remaining 10%. Unusual circumstances will be considered for extended deadlines. Upon receipt of the reports, withheld funds will be sent to the grantee institution.

All final reports are due no later than one year after the last funded grant year.

## **11. Policy on Delinquent Financial/Research Reports**

The Foundation reserves the right to deny additional grants to any institution where after proper notification, an investigator has not submitted his/her final reports, and/or the financial officer has not submitted the final report of expenses, as required by MTF. This policy will be enforced when reports are one year past the final due date. Upon receipt of these reports, the institution shall again become eligible for MTF grants.

## 12. MTF Policy on Animals or Humans in Research

The approval form from your institution's IACUC, IRB or other relevant administrative body should directly follow all written proposals that use human or animal subjects as part of the research to be performed. If formal approval is still pending for your project at the time of submission, an acknowledgement receipt from the appropriate institution research office must be supplied. No proposal that is submitted without either the appropriate committee approval or acknowledgement of concurrent institutional review will be funded.

Use of human subjects in any protocol must be justified. All clinical protocols using human subjects for research must be reviewed by the institutional IRB committee(s) where the project will be administered. MTF grantees are entrusted to assure adequate protection of human subjects. NIH regulations regarding human subjects should be followed.

Use of animals and number requested for project must be justified by the grantee's institution. All animals used in research supported by MTF grants must be acquired lawfully and be transported, cared for, treated and used in accordance with existing laws, regulations and guidelines. Decisions as to the kind and sources of animals that are most appropriate for particular studies must be made by scientists and institutions. MTF policy requires that such decisions be subject to institutional and peer review for scientific merit and ethical concerns and that appropriate assurances be given that NIH principles governing the use of animals are followed.

## 13. Policy on Grant Intellectual Property

Each application should be accompanied by the following non-negotiable commitment, under the signature of PI 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 shall have the following rights:

**(A) Notice.** Both the investigator and his/her academic institution shall deliver written notice to MTF 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 with respect to the product, intellectual property or commercialization.

**(B) Right-of-First Offer.** MTF 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 delivers advice to the investigator or his/her institution of its interest in commercializing such product or intellectual property, MTF 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's 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.

**(C) Allograft Supply.** With limiting the rights of MTF under Paragraph (b), the parties acknowledge and agree that MTF 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's customary terms and conditions attendant to such allograft supply. In the event of any Commercialization Notice, MTF 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 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 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.

#### **14. Publications and Presentations**

The Foundation encourages the publication of all research findings by MTF grant supported investigators. MTF also encourages participation in all appropriate scientific meetings, forums, and research consortiums. An acknowledgement statement should be included as a front-page footnote (or other locations determined by the Journal editors) of any publication supported by MTF grant funds, or it should be displayed prominently upon the base of any poster or visual presentation. Please include the following statement:

*"Supported by a Grant from the Musculoskeletal Transplant Foundation".*

No information regarding grant supported projects, their status or findings will be made known for any reason to any party outside of The Musculoskeletal Transplant Foundation for any purpose prior to publication without the written consent of the Principal Investigator. However, the Project Title, Principal Investigator, Institution name, and the amount of award may be used in MTF promotional materials or in required Sunshine reporting.

The Foundation must be sent reprints of all papers and publications resulting from MTF support, including those that appear after funding has expired. Reprints are preferred in electronic form.

#### **15. Policy on Transfer of Grant**

If the principal investigator moves institutions after the grant is awarded, the request to take the grant to the new institution will be considered by MTF. The investigator must also submit a letter enclosing resources, personnel and curriculum vitae of investigators at the new institution. The PI must obtain (MTF) Board approval as well as acknowledgement prior to transfer of funding.

For the *WF Enneking Career Development Award only*, if the grant has not started at the first institution, the grant will be cancelled. The principal investigator can re-apply from the new institution for the following year’s funding if it is an MTF Academic Member institution. If the grant has started, any unexpended funds must be returned to MTF.

**16. Policy on Changing Aims of Grant**

If the principal investigator and collaborators find that the original aims of the grant cannot be accomplished, and that to continue the project substantial changes in aims or methodology must be considered, the principal investigator must write to MTF, requesting permission to change the procedure and state the reasons for the change

**17. Duplicated Research Support**

It is MTF’s policy that if a project is funded by more than one source during the course of MTF’s grant, the PI must inform MTF of that occurrence. The PI must then choose one of the funding sources. If MTF is not selected, all granted monies must be returned to MTF immediately.

**18. Sunshine Compliance**

MTF may be obligated to report awarded grants under applicable Sunshine reporting regulations. Items that MTF includes in this report include, without limitation, the Principal Investigator’s name, institution, and NPI number, as well as the grant title and award amount. Therefore, all grant applications from clinicians (i.e., M.D.s, D.O.s, D.D.S.s, etc.) with an active U.S. Medical License must include the PI’s NPI number in the appropriate box on the application.

**19. Acceptance of Policies and Funding Restrictions**

All MTF awards are subject to the terms and conditions, cost principles, intellectual property policy, commercialization policy and other considerations described in the Administrative Policies & Procedures guide (this document) and any program and/or application specific policies in specific grant RFPs. Documentation of regulatory approvals or pending application status (e.g., Institutional Review Board, Recombinant DNA Advisory Committee, IACUC Review boards, etc.) must be provided to MTF as part of the application package.

**20. Correspondence**

<b>For routine inquiries regarding the grant process</b>	<b>For inquiries of a confidential or scientific nature</b>
Ms. Ava DeGrose Grant Administrator Musculoskeletal Transplant Foundation 1232 Mid Valley Drive Jessup, PA 18434 (570) 496-3436 <a href="mailto:ava_degrose@mtf.org">ava_degrose@mtf.org</a>	Jeffrey Cartmell, Ph.D. Assoc. Director, Intellectual Property & Grants Musculoskeletal Transplant Foundation 1232 Mid-Valley Drive Jessup, PA 18434 (732) 661-2151 <a href="mailto:jeffrey_cartmell@mtf.org">jeffrey_cartmell@mtf.org</a>