



MTF BIOLOGICS GRANT PROGRAM - 2020

ADMINISTRATIVE POLICIES AND PROCEDURES

MTF Biologics offers research grants to fund novel research in the fields of allograft transplantation and allograft science which have a high likelihood of impact on scientific discipline and/or on patient care.

These grants are intended to provide support for research projects focused on novel uses of allografts or allograft-derived materials for biologic repair and reconstruction with a strong clinical translation component in the following areas: Orthopaedics, Spine, Wound Care, the use of Adipose tissues, the use of Placental tissues, or other novel allograft transplant technologies.

Proposed studies should focus on innovative translational and clinical research in the fields of tissue allograft transplantation and science, novel uses of allografts, combination with other biomaterials to enhance properties, and transformative regenerative medicine technologies relying on allograft tissues and matrices. Proposals focusing solely on autologous grafts and synthetic applications which do not incorporate investigation of allograft use and/or where the allograft is solely a scaffold for autograft (including cells) or other non-allograft materials are beyond the scope of this grant program.

Both clinical and translational research projects will be considered for funding. Translational topics of interest related to tissue allograft science and/or transplantation include but are not limited to:

- Use of allograft tissues and/or human-derived biologics in tissue engineering, regenerative medicine, or combination products
- Technologies aimed at improving biologic behavior of allografts, such as viable allografts
- Novel uses of HCT/P allografts, including adipose-derived and placental-derived tissues in novel indications
- 3D Printing using allograft-derived materials and/or biologics
- Utilization of precision medicine, molecular biology and/or genomics applications to develop patient-matched allografts.

Examples of clinical technologies of interest include but are not limited to:

- Use of allograft biologics in bone repair and fusion
- Sports Medicine
- Wound Care
- Diagnostics and treatment algorithms related to the use of allografts
- Placental-derived tissues
- Adipose-derived tissues
- Pediatric Oncology / General Oncology
- Limb salvage (via retrospective studies)
- Health Economics related to clinical outcomes with allografts.

MTF Biologics will consider research proposals for the 2020 research grant program in the following categories:

1. **Clinical Science Grant:** The objective of the Clinical Science Grant is to investigate clinical outcomes and/or cost efficiencies to support allograft use in clinical practice with the potential to affect or benefit clinical decision-making. Types of studies that MTF Biologics is interested in funding include but are not limited to retrospective clinical studies, data mining, creation of registry data and health economic studies. Any health economic studies should consider overall cost(s) of all proposed study groups. Funded clinical studies could be used as a basis for future, more robust grant submissions to other agencies.

A Clinical Science Investigator is one who has completed doctoral, residency, and/or fellowship training (for Ph.D.'s and M.D.'s as applicable). The applicant can be from any accredited institution or university.

Interested applicants can apply to either the Established Investigator track or the Junior Investigator track. 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, based upon track type.

2. **Extramural Research Grant:** The objective of this grant is to support innovative translational research which will assist in moving discoveries to the clinic. Proposed studies should focus on novel research in the fields of allograft transplantation, and/or allograft science, novel uses of allografts, allograft-derived materials or biologic and/or musculoskeletal reconstruction. Areas of interest include novel areas for use of allograft tissues, orthopaedics, spine, wound care, the use of adipose tissues or placental tissues.

Interested applicants can apply to either the Established Investigator track or the Junior Investigator track. 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, based upon track type.

3. **Dr. William F. Enneking Career Development Grant:** The MTF Biologics Dr. William F. Enneking Career Development Grant is intended to foster the development of outstanding orthopaedic clinician-scientists and enable them to expand their potential to make significant research contributions to their clinical field. It is expected that following this experience, the applicant will be able to pursue an independent and productive career in research and clinical medicine. MTF Biologics 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 Dr. William F. Enneking Career Grant, the applicant must be a post-Fellow M.D. or D.O. employed by an MTF Biologics Academic Member institution in an Orthopaedic Surgery department. The institution must have a well-established research and clinical career development program and qualified faculty in clinical and basic research to serve as mentors. If awarded, an applicant is expected to provide at least 40% effort towards the research project.

General Policies for All Grant Categories

1. Deadline Date for all Submissions: March 1, 2020.

The MTF Biologics Grants Office must receive all applications by March 1, 2020. Applicants are encouraged to submit applications before the due date to ensure they have time to make any required corrections necessary for a successful submission.

Organizations must submit applications via the MTF Biologics Grant portal. If errors must be corrected on a submitted application, a changed/corrected application must be submitted to MTF Biologics on or before the application due date. Changed/Corrected applications submitted after the deadline will be considered late, and at MTF Biologics’ discretion, the original application may be utilized for 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	Both New Applications and Resubmission Applications will be accepted. (Applications may be re-submitted one time)
Funds Availability and Anticipated Number of Awards	The number of grant awards is contingent upon MTF Biologics appropriations and the submission of a sufficient number of meritorious applications.
Award Budget	<p><u>Established Investigator Track</u>: Total awards are limited to \$300,000 over a three-year (36 month) period, with yearly awards limited to \$100,000.</p> <p><u>Junior Investigator Track</u>: Total awards are limited to \$100,000</p> <p><u>Dr. William F. Enneking Career Development Grant</u>:</p> <p>Total awards are limited to \$300,000 over the three-year period, with yearly awards limited to \$100,000.</p> <p><i>Indirect Costs are limited to 20% of the total award for all grants.</i></p>
Award Project Period	The scope of the proposed project should determine the project period. The maximum award period is three years for the applicants who are Experienced Investigators or applying to the Dr. William F. Enneking Career Development Grant. The maximum award period is one year for applicants who are Junior Investigators. <u>Two</u> six-month no-cost

	extensions at the end of the grant period may be approved by MTF Biologics if justified at that time.
Sunshine Reporting	MTF Biologics reports all applicable grants to the appropriate Sunshine databases.

3. Eligibility Information

a. Eligible Institutions:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- 501(c)(3) public charities whose sole mission is to support research at a specific private or public Institution 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. Investigator Eligibility:

Clinical Science Investigator: A Clinical Science Investigator is one who holds an academic appointment in a clinical department of an accredited academic medical center or institution.

Established Investigator: An Established Investigator is one who, as a PI, has received prior research funding from a Federal Agency or a Foundation at the R01 level (or equivalent), and has published in a peer-reviewed journal as the Principal Investigator.

Junior Investigator: A Junior Investigator is one whom has completed either their post-doctoral or residency training (for Ph.D.'s and M.D.'s, respectively) but has not previously received an R01 level grant (or equivalent) as a Principal Investigator (PI) from a Federal Agency or a private Foundation. Applicants whom are completing their residency and/or post-doctoral training are eligible to apply; however, such training must be completed prior to initial funding of the MTF Biologics Grant.

Dr. William F. Enneking Career Development Grant: The applicant must be M.D. or D.O. (from an accredited U.S. or Canadian medical school) working at an MTF Biologics Academic Member institution, and completed their final training from an accredited Residency and Fellowship program within five years of the funding start date. The institution must have a well-established orthopaedic research and career development program with qualified faculty in clinical and basic research to serve as mentors. An applicant who has received an R01 NIH grant or its equivalent as a Principal Investigator, is not eligible for the Dr. William F. Enneking Career Development Grant. Only applicants in the fields of Orthopaedic Surgery are eligible to apply for the Dr. William F. Enneking Career Development Grant.

4. Application Procedures and Policies

It is critical that applicants read and follow all application instructions in these Administrative Policies and Procedures as well as the instructions provided on the application itself, and any program-specific instructions noted in RFPs. 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.

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

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

All grant policies are non-negotiable.

The use of the provided applications forms is required. The total written research plan section must not exceed 8 pages. Do not use an Appendix to circumvent page limits.

Applications can be resubmitted one time for consideration. For resubmission of proposals, the prior critiques must be addressed as indicated in the application.

Application forms are available on the MTF Biologics website at the following URL: <https://www.mtfbiologics.org/grants> or by contacting the MTF Biologics Grants Office.

Submission Instructions:

Applications must be submitted via the MTF Biologics Grants web portal, accessible at the following URL: <https://www.mtfbiologics.org/grants>. Demographic data will be entered via the web portal. A single PDF file of the research plan and supporting documentation is required to be uploaded to the portal.

Upon receipt, applications will be evaluated for completeness by the MTF Biologics Grants Office and applicability to MTF Biologics' mission. Applications which 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. Applications that conflict with the Mission of MTF Biologics will not be reviewed.

The Mission of MTF Biologics is: We Save and Heal Lives, by Honoring Donated Gifts, Serving Patients, and Advancing Science.

Policies Specific to the Dr. William F. Enneking Career Development Grant

A member of the MTF Biologics' Board of Directors or Board of Medical Trustees *must* sponsor the applicant.

The applicant must work under the direction of a qualified mentor. Applicants must justify the need for a three-year period of mentored research experience and must be able to provide a convincing case that the proposed period of support will substantially enhance his/her career or will allow the pursuit of a novel or promising approach to a particular research problem.

Applicant must provide a statement on time to be allocated to the project each week during the 36 month time period, including percent of time and use of time. Applicant must also provide a statement of the relevance of the proposed project to the mission of MTF Biologics.

Applicants must be U.S. citizens or non-citizen nationals.

The award provides three consecutive 12-month appointments. At least 40% of the recipient's full-time professional effort must be devoted to the program and the remainder devoted to other clinical or teaching pursuits consonant with the objectives of this grant.

5. Research Plan

All applications must contain a detailed research plan. The decision on specific items for inclusion in each research plan is at the discretion of the Principal Investigator. Suggestions of which items to include in the Research Plan are contained in the Application Instructions.

6. Application Reviews and Notification of Awards

Each proposal received by MTF Biologics will be held in confidence by the administration and by all selected proposal reviewers. Proposals focusing solely on autologous grafts and synthetic applications which do not incorporate investigation of allograft use and/or where the allograft is solely a scaffold for autograft (including cells) or other non-allograft materials, or proposals which conflict with the Mission of MTF Biologics will not be reviewed.

Each application will be reviewed by at least two scientists and/or clinicians. The reviewers are selected based on their topic(s) of expertise and are anonymous to each other. All proposals for clinical research studies and the Dr. William F. Enneking Career Development will be reviewed by clinicians.

Each proposal is numerically evaluated for the following: A) is the application Innovative while challenging and/or seeking to shift current research or clinical practice paradigms; B) the need or potential Impact of the study as related to tissue transplant science, allografts and/or surgical reconstruction of tissues; C) the scientific Quality of the proposal (reasoning, methods, experimental design, etc.); D) the Ability to complete the investigation in a timely manner (includes appropriate equipment, facilities, preliminary work, or mastery of techniques, etc.).

The appropriateness of the proposed Budget is also critiqued but it is not scored as part of the numerical evaluation.

All proposals are reviewed by the MTF Biologics Board of Directors' Research Committee. The scores and reviewer comments are used to form recommendations to the MTF Biologics Board of Directors, who will then review and select the final proposals meriting award. All decisions of the MTF Board of Directors' regarding funding are final

MTF Biologics will notify each applicant of funding decisions by email in July 2020. All Principal Investigators 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 grant type and requested budget, starting August 1, 2020.

All recipients of MTF Biologics Grants will receive their support made in four equal 25% payments during the grant year. **The final 25% payment (for each grant year) will be made upon receipt of the required, Annual Scientific Report and Financial Report; both of which are due within 60 days of the end of the grant year (e.g., the first grant year will end on Aug. 1, 2021 and the reports are due by Sept. 30, 2021).**

For years 2 and 3 of multi-year grants, each funded year will begin on August 1, and funds will be released once the prior year's Scientific and Financial Reports have been received and reviewed by MTF Biologics.

Two, 6-month no-cost extensions are allowed as described in Section 9.

A payment schedule will be provided with the funding award letter.

8. Financial Policies / Expectation of Institutional Responsibilities:

The 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 biomedical 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
- Office equipment
- Lantern slides, color plates, etc.
- Hospital bed expense, nursing or related services, even though used for research studies.

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

Equipment purchased under MTF Biologics grants become the property of the institution, unless otherwise specified by MTF Biologics prior to termination of the grant or its extensions. Any requested equipment over \$1000 must be justified with the budget request.

9. Budget Policies

- 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 Biologics.
- Grantee must request permission and receive written approval from the MTF Biologics prior to making any changes to the approved budget or moving funds between budget categories.
- If a budget approved by MTF Biologics' Board of Directors is less than that requested in the application, new budget forms will be sent to grantee when notification of the 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.
- Grantee may terminate a grant prior to normal expiration date by notifying the Foundation in writing and stating the reasons for termination. All unexpended funds must be returned to the Foundation within sixty (60) days, together with a final report of expenditures and project status.
- MTF Biologics reserves the right to terminate grants at any time upon three months written notice. In such case, all unexpended funds less non-cancellable commitments must be returned to the Foundation within sixty (60) days, together with a final report of expenditures and project status.
- 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.
- No-Cost Extensions: If a grantee who has not completed the research project prior to expiration, and for just reason, the grantee may submit to MTF Biologics thirty days prior to expiration, a request for a six month no-cost extension, stating reason and requested period of extension. Only two, 6-month extensions may be requested per grant. If the grant project is not completed upon the agreed deadline, the PI will lose the remaining granted funds. Any unexpended funds in excess of \$100.00 at the completion of the grant must be returned to MTF Biologics.
- Salary: the recommended total salary level for MTF Biologics grants varies by grant mechanism. Total Salary includes all salary-related charges, e.g., wages, and fringe benefits. For the purpose of this policy, student tuition is considered a fringe benefit. Justification for Total Salary requests above the suggested level is required. The recommended total salary levels by grant type are:

- Extramural Research Grant: 35% of total grant award
- Clinical Sciences Grant: 50% of total grant award
- Dr. William F. Enneking Career Development Grant: 50% of total grant award
- Indirect Costs: The indirect cost (IDC) rate is based upon the total direct costs (DC). The indirect cost rate is capped at 20% of the requested total direct costs. (e.g., 20% = IDC/DC)

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.
- MTF Biologics encourages publication of all data generated by funded projects. Any paper, conference presentation or other publication resulting from the funded projects must carry the following acknowledgement: "Supported by a Grant from MTF Biologics". Reasonable publication fees, including those for open source journals, can be charged against the Grant, but should be limited to \$1,500/year.
- Reasonable travel funds can be charged against the grant. Travel funds should be limited to no more than \$1,500/year.

10. Progress Reports & Final Reports

Both Financial and Scientific Progress / Final Reports are required at the end of each grant year for all MTF Biologics Grants. For each grant year, all reports are due by August 1. The Principal Investigator is responsible for submitting the scientific progress report each granted year and the final report when the work has been completed. A financial report prepared and signed by the Institution's designated Financial Officer must accompany the scientific report.

Reporting Obligations:

Scientific Reports – Progress Reports: Scientific progress reports should be no more than 2 pages, and must address the progress made on each specific aim during the reporting period. Results should be provided in a concise manner. Appropriate rationale must be provided for any Aim which is not met. Any changes in the specific aims because of the progress to date must be justified.

Scientific Reports – Final Reports: The final report should summarize the work completed on the entirety of the grant, and should be between 5-10 pages in length. All reporting periods should include listing of any peer-reviewed publications or meeting presentations that report on the work supported by the grant.

Financial Report: 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 25% of dollars for any grant award year will be withheld if the Principal Investigator does not submit both a Scientific Report and a Financial Report for the reporting period until both documents are on file at the MTF Biologics Grants office. For the final grant payment, these reports should encompass the totality of the grant period. For no-cost extensions, these reports are due at the conclusion of the no-cost extension term. The Principal Investigator is responsible for acquiring the financial report from the appropriate financial officer at his or her institution. Upon receipt of the reports, withheld funds will be sent to the grantee institution.

All final reports are due no later than six months 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 Biologics. This policy will be enforced when reports are one year past the final due date.

12. MTF Biologics Policy on Animals or Humans in Research

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 Biologics grantees are entrusted to assure adequate protection of human subjects. NIH regulations regarding human subjects must 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 Biologics 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 should be made by scientists and institutions. MTF Biologics 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.

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

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13. MTF Biologics Policy on Grant Intellectual Property

Submission of a grant application to MTF Biologics indicates acceptance by the Principal Investigator and their Institution of the following non-negotiable commitment on Intellectual Property and Allograft Supply:

RIGHT-OF-FIRST NEGOTIATION; ALLOGRAFT SUPPLY

MTF Biologics shall have a right of first and exclusive negotiation to participate in the development and commercialization of any product or intellectual property resulting from work associated with the Grant, as follows:

- (A) Notice.** The investigator and his/her academic institution shall deliver written notice to MTF Biologics of the intended commercialization (the “Commercialization Notice”). The investigator and his/her academic institution shall promptly respond to reasonable requests for information made by MTF Biologics to permit MTF Biologics to evaluate its interest in the commercialization of the product or intellectual property.
- (B) Right-of-First Negotiation; Intellectual Property & Commercialization.** Within 90 days of receiving the Commercialization Notice, MTF Biologics shall advise the investigator or his/her academic institution of its interest in commercializing such product or intellectual property. The parties will then negotiate the respective rights of the development 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 for such commercialization will not be on terms (i) more favorable to the third party than those offered to MTF Biologics; or (ii) less favorable to institution than those proposed by MTF Biologics.
- (C) Right-of-First Negotiation; Allograft Supply.** Without limiting the rights of MTF Biologics under Paragraph (b), the parties acknowledge and agree that MTF Biologics will have the Right-of-First Negotiation to become the sole supplier of allograft materials or any other biologic material which MTF Biologics provides to end users to support the commercialization of any product or intellectual property covered by a Commercialization Notice (the “Supply Rights”). The parties will then negotiate the respective Supply Rights in good faith, and will use all reasonable efforts to agree upon terms, conditions and other provisions within 60 days of MTF Biologics’ advice regarding the Commercialization Notice (paragraph A). If no such agreement is reached within such period, neither the investigator nor his/her institution will be constrained in negotiating Supply Rights with another entity, except that an agreement with any other party for such Supply Rights will not be on terms (i) more favorable to the third party than those offered to MTF Biologics; or (ii) less favorable to institution than those proposed by MTF Biologics. 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 opt to supply allograft materials in connection with such commercialization, in which case MTF Biologics will not be obligated to supply allograft or biologic materials and neither the investigator nor his/her institution will be constrained in arranging for an alternative supply.

14. Publications and Presentations

MTF Biologics encourages the publication of all research findings that result from studies supported by the awarded grants. MTF Biologics also encourages participation in appropriate scientific meetings, forums, and research consortiums by the grantee(s) or his/her co-investigators. An acknowledgement statement must be included as a front-page footnote (or other location as determined by the Journal editors) of any publication supported by MTF Biologics grant funds, and it must be displayed prominently upon the base of any poster or visual presentation. The following acknowledgement statement must be included in publications derived from work supported by grant from MTF Biologics:

"Supported by a Grant from the MTF Biologics"

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 prior to publication without the written consent of the Principal Investigator. However, the Project Title, Principal Investigator, Institution name, and the amount of grant award may be used in MTF Biologics promotional materials or in required Sunshine reporting.

The Foundation *must* be sent reprints of all meeting abstracts, presentations, papers and publications resulting from MTF Biologics 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 Biologics. The investigator must also submit a letter enclosing resources, personnel and curriculum vitae of investigators at the new institution. The PI must obtain MTF Biologics approval as well as acknowledgement prior to transfer of funding. For transfer of funds, all unspent grant funds must be returned by the original institution to MTF Biologics for further distribution to the new institution.

For the *Dr. William F. Enneking Career Development Grant 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 Biologics Academic Member institution. If the grant has started, any unexpended funds must be returned to MTF Biologics.

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 Biologics, requesting permission to change the procedure and state the reasons for the change

17. Duplicated Research Support

It is MTF Biologics' policy that if a project is selected for funding by more than one funding source during the course of MTF Biologics' grant, the PI must inform MTF Biologics of that

occurrence. The PI must then choose one of the funding sources. If MTF Biologics is not selected, all granted monies must be returned to MTF Biologics promptly.

18. Sunshine Compliance

MTF Biologics is obligated to report awarded grants under applicable Sunshine reporting regulations. Items that MTF Biologics includes in this report include, without limitation, the Principal Investigator’s name, Institution, the grant title, the grant award amount and NPI numbers for both the Principal Investigator and their Institution. 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 Principal Investigator’s NPI number in the appropriate box on the application, and all grant applications from Principal Investigators at U.S. teaching hospitals must include the Institutional NPI number in the appropriate box on the application.

19. Acceptance of Policies and Funding Restrictions

All MTF Biologics 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 Biologics as part of the application package.

Policies outlined in this document are non-negotiable. It is the responsibility of the grant applicant and their institutions to understand all applicable policies associated with their grant applications. By submitting a grant application to MTF Biologics, the applicant and his/her institution indicate their acceptance of all grant policies.

20. Correspondence

For inquiries regarding the grant application process	For inquiries of a confidential or scientific nature
Ms. Christine Jenkins Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 07728 (732) 661-2159 christine_jenkins@mtf.org	Jeffrey Cartmell, Ph.D. Director, Intellectual Property & Grants 125 May Street Edison, NJ 07728 (732) 661-2151 jeffrey_cartmell@mtf.org