**MTF BIOLOGICS RESEARCH GRANT APPLICATION 2020**

Application Checklist (For Reference Only)

☐ Face Page

☐ Financial Officer/Other Investigators/Miscellaneous Grant Information

☐ Signature Page

☐ MTF Biologics Policy on Grant Intellectual Property

☐ MTF Biologics Grant Keyword Selection List

☐ Abstract of Research Plan

☐ Innovation Statement

☐ Personnel & Facilities Disclosure Form

☐ Budget Form and Budget Justification

☐ Prior Research Disclosures

☐ Biographical Sketch - Principal Investigator

☐ Biographical Sketches – Co-Investigator(s)

☐ Support Letters

☐ Research Plan

 (Items a – d, Not to exceed 8 pages; Item h is not to exceed 2 pages)

a) Specific Aims

b) Background, Significance and Rationale

c) Preliminary Studies/Progress Report

d) Research Design and Methods

e) Human Subjects and/or Vertebrate Animals (include institutional approval letter)

f) Literature Cited (2 pages max.)

g) Response to Prior Critiques (Resubmissions Applications Only; 1 page max.)

h) Support Items for the Dr. William F. Enneking Career Development Grants
(if applicable; 2 pages max.)

1. Career Goals
2. Time Allocated to the Project

☐ Support Letters

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| **MTF Biologics Research Grant Application 2020** |
| **Application Track**: \_\_\_\_ Clinical Research \_\_\_\_ Extramural Research \_\_\_\_ Career **Investigator Type:** \_\_\_\_ Junior \_\_\_\_ Established**Resubmission Application:** \_\_\_\_Yes \_\_\_\_ No |
| 1. **PROJECT TITLE** |
| 2. Dates Of Proposed Period Of Support:  (*MM/DD/YY)*From: Through:  | 3. Costs Requested for Each Year | 4. Total REQUESTED Costs |
| Year 1 | Year 2 | Year 3 |
|  |  |  |
| **5. Principal Investigator & INSTITUTION Information** |
| 5a. Name: Last:First:Middle: | 5b. Degrees:  | 5c. NPI #  |
| 5d. Position Title:  | 5e. Mailing Address StreetCityStateZipe-mail |
| 5f. DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT |
| 5g. E-Mail Address | 5h. TELEPHONE (Area code, number, extension)Tel.:  |
| 6a. Applicant Organization: | 6b. ORGANIZATION ADDRESS:StreetCityStateZip |
| 6c: NPI # for INSTITUTION: |
|  |
| 7. Department ChairmanLast:First:Middle:Title:Street Address:City:State:Zip:Phone:Email: |
| 8. Official Signing for Applicant Organization *(Administrative Official to be notified if Award is Made)*Last:First:Middle:Title:Street Address:City:State:Zip:Phone:Email: |

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| **11. FINANCIAL OFFICER INFORMATION** |
| 11a. FINANCIAL OFFICERLast:First:Middle:Title:Street Address:City:State:Zip:Phone:Email:  |
| 11c. PAYMENT INFORMATION**Payee For Check:** **Address For Check:**Street Address:City:State:Zip: |
| **12. CO-INVESTIGATOR (CO-I) INFORMATION** |
| 12a. Co-I 1Name: Last:First:Middle: | 12b. Degrees:  | 12c. NPI #  |
| 12d. Position Title:  | 12e. Mailing Address Street Address:City:State:Zip:e-mail |
| 12f. DEPARTMENT | 12g. E-Mail Address |
| 12h. TELEPHONE (Area code, number, extension)Tel.:  | 12i. Co-Investigator Signature |
| 13a. Co-I 2 Name: (Last, First, Middle) Last:First:Middle: | 13b. Degrees:  | 13c. NPI #  |
| 13d. Position Title:  | 13e. Mailing Address Street Address:City:State:Zip:e-mail |
| 13f. DEPARTMENT   | 13g. E-Mail Address |
| 13h. TELEPHONE (Area code, number, extension)Tel.:  |
| ***Use Continuation Page if Necessary to include more than two Co-Investigators*** |
| **14. MISCELLANEOUS GRANT INFORMATION** |
| 15. Human Subjects: ­­­\_\_\_ Yes \_\_\_ No15a. If “YES”, Exemption #:  or IRB Approval Date: \_\_\_\_ Full IRB \_\_\_\_ Expedited Review | 16. Vertebrate Animals: \_\_\_\_ Yes \_\_\_\_ No16a. If, “YES”, IACUC #16b. Animal Welfare Assurance #:  |

**MTF Biologics 2020 Grant Application Signature Acknowledgements**

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| --- | --- |
| **Project Title:**  |  |
| **Principal Investigator Name:**  |  |
| **Institution:**  |  |

Principal Investigator & Department Chair:

*I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me or my institution to administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application*

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Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department Chair Date

Institutional and Financial Officer:

*I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with MTF Biologics terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me or my institution to administrative penalties*.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Officer Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Financial Officer Date

Co-Investigator(s):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator Date

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Co-Investigator Date

(Add additional Co-Investigator lines as required)

**Policy on Grant Intellectual Property: RIGHT-OF-FIRST NEGOTIATION; ALLOGRAFT SUPPLY**

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:

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:

1. **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.
2. **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.
3. **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.

**MTF Biologics Grant Keyword Selection List**

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, please type in one appropriate keyword.

This list will be used to assign your grant proposal to the appropriate reviewers.

\_\_\_\_\_\_ Adipose

\_\_\_\_\_\_ Bio-Reconstruction

\_\_\_\_\_\_ Biomaterials, Bioconstructs, Scaffolds, or Matrix

\_\_\_\_\_\_ Bone Repair, Healing or Incorporation

\_\_\_\_\_\_ Cartilage or Osteochondral

\_\_\_\_\_\_ Genetics or Gene Therapy & Delivery

\_\_\_\_\_\_ Growth Factors

\_\_\_\_\_\_ Health Economics

\_\_\_\_\_\_ Ligaments or Tendons

\_\_\_\_\_\_ Mechanics or Biomechanics

\_\_\_\_\_\_ Meniscus

\_\_\_\_\_\_ Molecular Biology or Cellular Signals

\_\_\_\_\_\_ Muscle

\_\_\_\_\_\_ Nerve

\_\_\_\_\_\_ Physiochemical or Immunochemical Tolerance

\_\_\_\_\_\_ Placental tissue

\_\_\_\_\_\_ Precision Medicine

\_\_\_\_\_\_ Regenerative Medicine

\_\_\_\_\_\_ Soft Tissue Grafts, Fascia, or Mesh

\_\_\_\_\_\_ Stem Cells

\_\_\_\_\_\_ Tissue Banking, Processing, Storage, or Sterilization

\_\_\_\_\_\_ Vascular Marrow

\_\_\_\_\_\_ Viable Allografts

\_\_\_\_\_\_ Wound Healing

\_\_\_\_\_\_ Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ABSTRACT OF RESEARCH PLAN:** Provide a **one page abstract** with up to five underlined key phrases to highlight the project. The abstract should be a stand-alone item that provides some background and rationale to the proposed research; hypotheses; specific aims; experimental design; preliminary data and potential outcomes.

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| MTF Biologics Research Grant Application 2020 |
| Project Title: |  |
| PI Name: |  |
| Institution: |  |
| Abstract details here: |

**INNOVATION STATEMENT:** Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. 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.

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| Statement Details here: |

**PERSONNEL & FACILITIES DISCLOSURE FORM**

**KEY PERSONNEL.** *Use continuation pages as needed to provide the required information in the format shown below.*

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| **Name** | **Organization** | **Role on Project** |
|  |  | Principal Investigator |
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**PERFORMANCE SITE(S)** *(organization, city, state) Indicate where the work described in the Research Plan will be conducted. If there is more than one performance site, list all the sites, including V.A. facilities and provide an explanation of what work will be conducted at each facility…*

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| Performance Site Details here: |

**BUDGET FORM**

**SALARIES,WAGES AND FRINGE BENEFITS (list all personnel associated with project)**

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| **PERSONNEL** | **RESPONSIBILITIES** | **% OF TIME** | Year 1 | Year 2 | Year 3 | Total |
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|  SUBTOTAL |  |

**PERMANENT EQUIPMENT (Justification should be appended for items over $1000.00)**

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| **DESCRIPTION OF ITEM/EQUIPMENT** | Year 1 | Year 2 | Year 3 | Total |
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**CONSUMABLE SUPPLIES**

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| **DESCRIPTION OF SUPPLIES** | Year 1 | Year 2 | Year 3 | Total |
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|  SUBTOTAL |  |

**ANIMALS (incl. ANIMAL CARE) AND/OR CLINICAL EXPENSES**

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| **DESCRIPTION OF SUPPLIES** | Year 1 | Year 2 | Year 3 | Total |
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|  SUBTOTAL |  |

**ALL OTHER EXPENSES**

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| **DESCRIPTION OF SUPPLIES** | Year 1 | Year 2 | Year 3 | Total |
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|  SUBTOTAL |  |

**TOTAL EXPENSES**

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| **COST CATEGORY** | Year 1 | Year 2 | Year 3 | Year 1-3 Subtotal |
| **SALARY**  |  |  |  |  |
| **EQUIPMENT** |  |  |  |  |
| **CONSUMABLES** |  |  |  |  |
| **ANIMALS** |  |  |  |  |
| **ADDITIONAL EXPENSES** |  |  |  |  |
| **Total Subdirect Expenses $** |  |
| **Total Indirect Expenses $** |  |
| **Indirect Expenses %** |  |
|  **TOTAL REQUESTED** |  |

**BUDGET JUSTIFICATION:** *Follow the budget justification instructions in the MTF Biologics guidelines.
Use continuation pages as needed.*

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| Budget Justification here: |

**PRIOR RESEARCH DISCLOSURES**

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| **PRIOR MTF BIOLOGICS GRANT SUPPORT** |
| **TITLE OF PROJECT** | **AMOUNT** | **PERIOD OF SUPPORT** |
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| **OTHER RESEARCH SUPPORT RELEVANT TO THIS PROJECT** |
| **TITLE OF PROJECT** | **SOURCE** | **AMOUNT** | **PERIOD OF SUPPORT** |
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| **ADDITIONAL SUPPORT TO INVESTIGATORS** |
| **TITLE OF PROJECT** | **SOURCE** | **AMOUNT** | **PERIOD OF SUPPORT** |
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**BIOGRAPHICAL SKETCH: PRINCIPAL INVESTIGATOR**

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| **NAME / TITLE / DEPARTMENT / NATIONALITY** |
| **Name of Principal Investigator** | **Title** | **Department Affiliation** | **Present Nationality(If Non-US Citizen, Please indicate status)** |
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| **TRAINING AND EDUCATION (Begin with Baccalaureate training include Post-Doctoral and clinical training – if applicable)** |
| **INSTITUTION** | **Location** | **Degree** | **Year Conferred** |
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| **MAJOR RESEARCH INTEREST** |
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| **RELATIONSHIP TO PROPOSED PROJECT** |
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| **OTHER RESEARCH SUPPORT** |
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| **RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position and list ALL experience relevant to project, Include Publications)** |
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**BIOGRAPHICAL SKETCH: CO-INVESTIGATOR**

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| **NAME / TITLE / DEPARTMENT / NATIONALITY** |
| **Name of Co- Investigator** | **Title** | **Department Affiliation** | **Present Nationality(If Non-US Citizen, Please indicate status)** |
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| **TRAINING AND EDUCATION (Begin with Baccalaureate training include Post-Doctoral and clinical training – if applicable)** |
| **INSTITUTION** | **Location** | **Degree** | **Year Conferred** |
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| **MAJOR RESEARCH INTEREST** |
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| **RELATIONSHIP TO PROPOSED PROJECT** |
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| **OTHER RESEARCH SUPPORT** |
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| **RESEARCH AND/OR PROFESSIONAL EXPERIENCE (Start with present position and list ALL experience relevant to project, Include Publications)** |
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**MTF Biologics 2020 Grant Application - Research Plan
(8 pages max.)**

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| --- | --- |
| **Project Title:**  |  |
| **Principal Investigator Name:**  |  |
| **Institution:**  |  |

BEGIN RESEARCH PLAN