

# FY23 Advanced Medical Technology Initiative (AMTI) Program Documentation – AMTI

United States Army Medical Research and Development Command (USAMRDC) Telemedicine and Advanced Technology Research Center (TATRC)





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### **AMTI Overview**

#### Mission:

Advanced Medical Technology Initiative (AMTI) Program facilitates bottom-up technology innovation while simultaneously informing top-down acquisition throughout Military Medicine. Program execution encompasses small funding investments at the facility/individual level in two distinct categories: Rapid Innovation Funding (RIF) and Extended Innovation Funding (EIF) for which the period of performance for each category is limited to 6 and 18 months respectively.

### Scope:

Identification, exploration, and demonstration of key technologies and enabling biomedical principles required to overcome technological barriers that are medically and militarily unique.

#### Motto:

Explore, Integrate, Innovate, Automate, Deliver

### **Objectives:**

Advanced Medical Technology Initiative (AMTI) Program facilitates bottom-up technology innovation while simultaneously informing top-down acquisition.

- Demonstrate emerging medical technologies and documenting their impact on PERFORMANCE (Lethality), READINESS, COST, ACCESS, QUALITY, and SAFETY through a bottom-up (provider/MTF level) approach.
- Provides leadership with medical tech-surveillance capability

### Purpose:

The AMTI is focused on identifying, exploring, and demonstrating key technologies and enabling biomedical principles required to overcome technological barriers that are medically and militarily unique.

This initiative plays a vital role in the fulfillment of these objectives to include advanced technology development, demonstration and validation of important new technologies and procedures. It is important to note that the AMTI Call for Proposals utilizes Defense Health Program Operations and Maintenance (DHP O&M) or Operations Maintenance, Army (OMA) funding and NOT appropriate for projects conducting research and development, which should be funded with 2-year Research Development Testing and Evaluation (RDT&E) dollars. DHP O&M/OMA funds may fund projects that involve analysis, tests and evaluations – think of a process improvement process or answer the questions "can I use/adapt this technology in/for my work environment". Examples of RDT&E projects include multi-year medical research, product development and drug/device clinical trials.

Submissions to the AMTI Call for Proposals should be innovative, non-duplicative, acquisition sensitive, collaborative and implementable within AMTI funding timeframes.

Each submission will be evaluated based upon the following criteria: military relevance, innovative concept, metrics for success and potential return on investment (ROI). Those Innovators who's Preproposals are evaluated to be of greatest interest will be invited to submit a full proposal, which will be evaluated by the AMTI Full Proposal Review Panel. Funding is made available on a year by year basis and follow-on funding is not authorized.

Questions concerning the preparation of submissions can be emailed to the AMTI Proposals Management office at usarmy.detrick.usamrdc.list.aamti-pm@mail.mil .

# **Types of Funding**

# **Rapid Innovation Funding (RIF)**

AMTI RIF Funding is for technology demonstration projects with a 6 month performance period. Submissions are accepted on an ongoing basis. At the completion of the 6 month period Innovators are required to provide a final report and a QUAD chart. This type of funding is ideal for performance improvement projects to assess the value of a new technology. Knowledge and material products resulting from the initial funding will be collected for three years post final report.

# **Extended Innovation Funding (EIF)**

Extended Innovation Funding (EIF) is for technology evaluation projects with an 18 month or less performance period that may require Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) approval and/or contract support. Submissions are accepted from January -April this year and awards are typically made in September. An interim report is due at 9 months and a final report and QUAD chart is due at 18 months. Knowledge and material products resulting from the initial funding will be collected for three years post final report.

# **RIF Timeline**

Rapid Innovation Proposals are accepted throughout the year. Proposals are reviewed on a case-by-case basis and are awarded as funding becomes available.

# **EIF Timeline**

| Date(s)                     | Milestone   |
|-----------------------------|---|
| 31 January 2022             | Opening Date for Preproposal Submissions                      |
| 15 April 2022               | Closing Date for Preproposal Submissions                      |
| 22 April – 3 June 2022      | Preproposal Evaluations                                       |
| 22 June 2022                | Opening Date for Full Proposal Submissions (Invitation Only)  |
| 29 July 2022                | Closing Date for Full Proposal Submissions                    |
| 2 August - 9 September 2022 | Full Proposal Evaluations                                     |
| 15 September 2022           | Full Proposal Evaluators meeting-funding recommendations made |

### **Areas of Focus**

#### Readiness –

- Develop tools, methods, and measures to better address the mental, physiological, and social factors that affect the stress response, resilience, fitness, performance, and recovery.
- Develop innovative, valid, and reliable tools to train, assess, and monitor mental and physical fitness training at the individual, unit, and organization levels in real-time.
- Develop valid and reliable tools to select for critical positions that require high resiliency and resistance to stressors.
- Cost reduce the cost of delivering care, enhance communication, knowledge management and decision support.
- Performance improve total force fitness, social, financial, physical, ethical and cultural environments.
- Access reduce the time it takes to access care and critical specialty intervention, improve communication for the direct care system
- Quality improve the skills and efficiency of care providers, leverage medical research and logistics management
- Safety improve the quality and safety of care, enhance communication, knowledge management and decision support.

Any innovative technologies demonstrated through the AMTI must be able to leverage enterprise-level solutions and demonstrate alignment with current strategic plans that are in place. Innovators must be able to identify the problem to solve in current services and the potential solution.

### **Roles in the AMTI Submission System**

### **Innovator:**

An Innovator is anyone who is associated with the project that has a role to play in the planning execution and management of the project. There should be at least one lead and active Innovator on all submissions and projects. There is not a limit to the Innovators that can be listed. Innovators must be added at the time of proposal submission and additional Innovators can be added at any time.

Innovators names should not be included unless they are aware of the project and fully support the work proposed. The name, rank (if applicable), email, title, corps, phone number and facility should be entered. Innovators will receive email correspondence on proposals award, due dates for reports and can view the record but cannot access documents within a record. Multiple Innovators can be added but only one can be identified as the primary Innovator who is responsible for completion of the proposed project.

### **Submitter:**

A Submitter is anyone who is responsible for the submission of documents and the management of the AMTI record from proposal to project execution. There should be at least one lead and active Submitter at any given time but must be approved by the AMTI PM if they are added after the initial proposal is created. There is not a limit to the number of Submitters on an AMTI record. Submitters must be added at the time of proposal submission and additional Submitters can be added at any time. To become a Submitter, applicants must register their CAC with the AMTI Proposal Submission System and complete the SAAR DD2875 and submit it to the MRDC Security officer. Once permission is granted they can access the AMTI proposal submission system and submit proposals, reports, request for extensions and financial information.

### **Eligibility**

### **AMTI**

The AMTI Call for Proposals is open to military treatment facilities or operational facility personnel, military and civilians only. Once funding is transferred, the awardee must be able to fully manage and execute the funding. Contractors can support a proposal but they cannot sponsor the proposal or act as a lead Innovator. Contractors can obtain a Submitter account if they have a current CAC card and a milnet computer to access the AMTI Proposal Submission System. Once they have an account they can upload any required administrative documentation but the Lead Innovator must be a military or civilian assigned to a military organization as they are responsible for all aspects of the project.

Collaboration with industry, academia and other military services is permitted. To support collaborative work with other organizations and agencies, contracts may need to be established and managed by the Innovator to complete the AMTI project.

Facilities are awarded funding, the funding is not awarded to individual Innovators. If the original Innovator is unable to complete the proposed project for any reason then the awarded facility must designate another Innovator to complete the proposed work. Government contractors cannot be responsible for AMTI projects.

Innovators should meet certain minimum standards pertaining to institutional support, financial resources, and record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations. Each proposal must include a list of infrastructure, equipment, personnel and subjects that would have to be acquired with an estimated time needed to acquire each.

There should also be a disclosure of how soon the project could start from the provision of funds, based upon the above acquisition requirements. The local Commander is now required to provide a signed letter stating they are aware of the AMTI proposal submission and confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and command perspective. These letters should be uploaded at the time of initial proposal submission for RIF and at FULL PROPOSAL phase for EIF. Innovators are also encouraged to engage the Defense Health Agency (DHA) clinical community members with subject matter expertise in the area of the proposal and obtain a letter of support.

# **Proposal Submissions**

### **AMTI Proposal Submission System**

All documentation is now required to be submitted directly through the AMTI Proposal Submission System (<a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a>). Internet Explorer is the best browser to use in accessing the AMTI Proposal Submission System.

An AMTI Proposal Submission System account must be requested and is required one week prior to the AMTI EIF deadline. New accounts will not be issued after this time as they cannot be processed prior to the submission deadline.

Access to the system can be gained by going to the AMTI Proposal Submission System site at https://tatrc.amedd.army.mil/AMTI/Default.aspx.

A current CAC and milnet computer to access are required to submit a proposal and maintain an AMTI project account. Proposals will not be accepted through email. Innovators/Submitters who have previously submitted AMTI proposals can submit proposals through the following link <a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a>

New Innovators/ Submitters must complete the following steps to submit an AMTI EIF or RIF Proposal:

Step 1) Register at: <a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a>

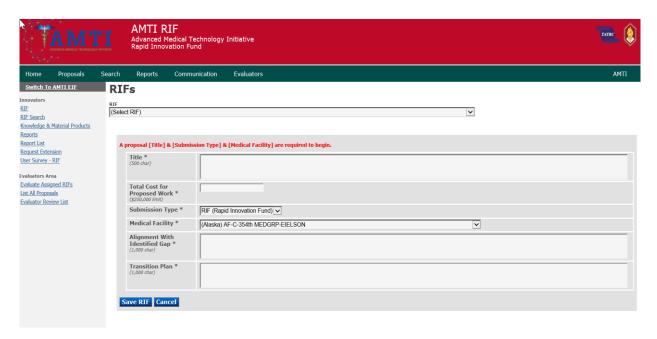
Step 2) Fill out a SAAR (linked to after registration) and submit to listed Security Officer

The SAAR will be reviewed by a member of USAMRDC security team and access will be activated by a member of our technical team. You will be notified by email when your account is active. Once notified that an account is active users can return to the AMTI Proposal Submission System at <a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a> and the AMTI SharePoint link page, which can be accessed at <a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a>.

Once an account has been obtained from the AMTI Proposal Submission System, Innovators/Submitter can enter into either the AMTI Proposal Submission EIF or RIF sites to submit a proposal.

# **Rapid Innovation Fund (RIF) Submission Process:**

Proposals are accepted year round at the RIF site. Note character count is different from a Word document when cut and pasted into the AMTI system so you may have to adjust your text once input into the AMTI Proposal System.



# **Proposal Template for the Rapid Innovation Funding (RIF):**

**Title:** [Limit to 250 characters]

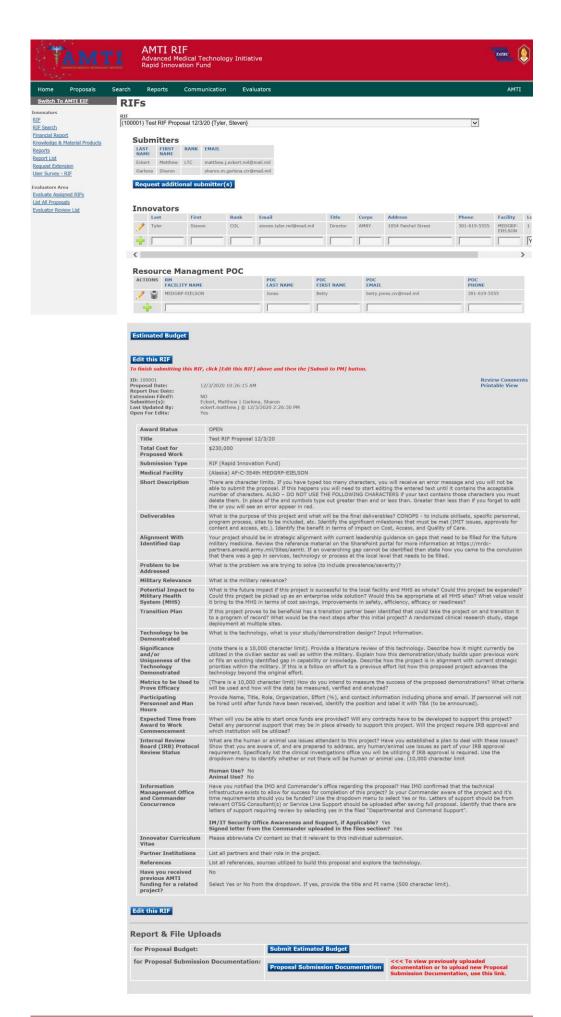
Total Cost for Proposed Work: (Do not use commas or decimal points only enter numerical values.)

**Submission Type: RIF** 

Medical Facility: (Choose from the drop down menu)

Alignment with Identified Gap (1,000 character limit): Your project should be in strategic alignment with current leadership guidance on gaps that need to be filled for the future of military medicine. Review the reference material on the SharePoint portal for more information at <a href="https://mrdc-partners.amedd.army.mil/sites/AAMTI/">https://mrdc-partners.amedd.army.mil/sites/AAMTI/</a>. If an overarching gap cannot be identified then state how you came to the conclusion that there was a gap in services, technology or process at the local level that needs to be filled.

**Transition Plan\* (1,000 character limit):** If this project proves to be beneficial, has a transition partner been identified that could take the project on and transition it to a program of record? What would be the next steps after this initial project? A randomized clinical research study, stage deployment at multiple sites.



**Innovator:** (Last Name, First Name, Rank, Email, Title, Corps, Address, Phone, Facility, Lead, Active)

### Additional Innovators (There is no limit.):

(Last Name, First Name, Rank, Email, Title, Corps, Address, Phone, Facility, Lead, Active)

**Resource Manager:** ((RM Facility Name, POC Last Name, POC First Name, POC Email, POC Phone)

Short Description: [Abstract] (1,000 character limit spaces included) There are character limits. If you have typed too many characters, you will receive an error message and you will not be able to submit the proposal. If this happens you will need to start editing the entered text until it contains the acceptable number of characters. NOTE: DO NOT USE THE SYMBOLS < OR >. If your text contains those symbols you will see an error appear in red; you then must delete the symbols and type out "less than" or "greater than" respectively

**Deliverables (1,000 character limit):** What is the purpose of this project and what will be the final deliverables? Provide CONOPS - to include skillsets, specific personnel, program process, sites to be included, etc. Identify the significant milestones that must be met (IMIT issues, approvals for content and access, etc.). Identify the benefit in terms of impact on Cost, Access, and Quality of Care.

**Problem to be addressed (10,000 character limit):** What is the problem you are trying to solve (to include prevalence and severity)?

**Military Relevance (10,000 character limit spaces included):** How will the military benefit, what military requirements does it address?

**Potential Impact to the Military Health System (MHS) (1,000 character limit)**: What is the future impact if this project is successful to the local facility and MHS as whole? Could this project be expanded? Could this project be picked up as an enterprise-wide solution? Would this be appropriate at all MHS sites? What value would it bring to the MHS in terms of cost savings, improvements in safety, efficiency, efficacy or readiness?

**Technology to be demonstrated (10,000 character limit spaces included):** What is the technology? What is your study/demonstration design?

**Significance and/or Uniqueness of the Demonstrated Technology (10,000 character limit spaces included)**: Provide a literature review of this technology. Describe how it might currently be utilized in the civilian sector as well as within the military. Explain how this demonstration/study builds upon previous work or fills an existing identified gap in capability or knowledge. Describe how the project is in alignment with current strategic priorities within the MHS. If this is a follow on effort to a previous effort list how this proposed project advances the technology beyond the original effort.

Metrics to be used to Prove Efficacy (10,000 character limit spaces included): How do you intend to measure the success of the proposed demonstrations? What criteria will be used and how will the data be measured, verified and analyzed?

**Participating Personnel & Man Hours (10,000 character limit spaces included):** [Name, Title, Role, Effort (%)] Note: Military and Civilian personnel should be identified as part of the proposed effort in this section but their salaries cannot be part of the budget.

**Expected Time from Award to Commencement (from receipt of funds) (10,000 character limit spaces included):** When will you be able to start once funds are provided? Will any contracts have to be developed to support this project? Detail any personnel support that may be in place already to support this project.

Institutional Internal Review Board (IRB) Protocol Review Status (10,000 character limit spaces included): What are the human or animal use issues attendant to this project? Have you established a plan to deal with these issues? Show that you are aware of, and are prepared to address, any human/animal use issues as part of your IRB approval requirement. Specifically list the clinical investigations office you will be utilizing if IRB approval is required. Use the dropdown menu to identify whether or not there will be human or animal use. Human Use: [Y/N] Animal Use: [Y/N]

Information Management Office (IMO) and Commander Concurrence: Have you notified the IMO and Commander's office regarding the proposal? Has IMO confirmed that the technical infrastructure exists to allow for success for completion of this project? Is your Commander aware of the project and its time requirements should you be funded? Use the dropdown menu to select Yes or No. Letters of support should be from relevant OTSG Consultant(s) or Service Line Support should be uploaded after saving full proposal. Identify that there are letters of support requiring review by selecting yes in the filed "Departmental and Command Support". Letters of support should be addressed to TATRC's Director, COL Jeremy C. Pamplin.

Innovator Curriculum Vitae (10,000 character limit or 1 page limit): Please abbreviate CV content so that it is relevant to this individual submission.

Partner Institutions: (10,000 character) List all partners and their role in the project.

**References (10,000 character limit)**: List all references, sources utilized to build this proposal and explore the technology.

Have you received previous AMTI funding for a related project? [Y/N, if yes, provide title and PI.] Have you submitted an interim and/or final report for previous efforts? Have you completed any previous efforts in a timely manner? Explain any timeline delays in previous efforts and interventions that will be utilized to avoid those potential issues in the future.

**Estimated Budget:** The budget button, located at the top of the proposal entry page after you have saved your proposal, links you to a page in which you must list each item/cost that you will incur for your project in the following categories Labor, Materials, Travel, and Direct Costs.

Military and civilian salaries should not be included in the budget but contractor salaries can be submitted. Travel for Military and Civilians can be listed in the budget, but it must be completed the year AMTI funding is received. Travel for contractors can be included and put on the ODCs for the contract. Indirect fees should be built into other costs and not separated out. Submitters are encouraged to work with their Resource Management Office early and often to ensure proper coordination and timely execution of funding should the project be awarded funding.

### **Extended Innovation Fund (EIF) Submission Process**

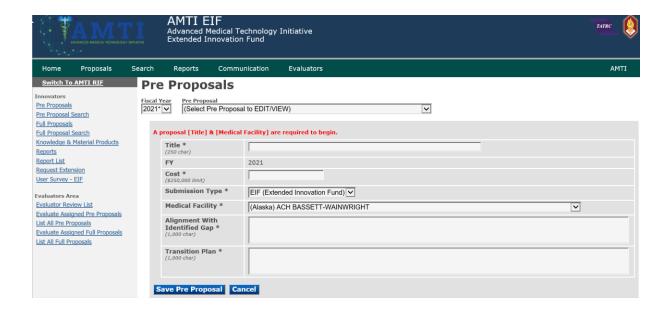
Initial submissions will be in the form of a preproposal submitted via a secure web site accessible from <a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a>.

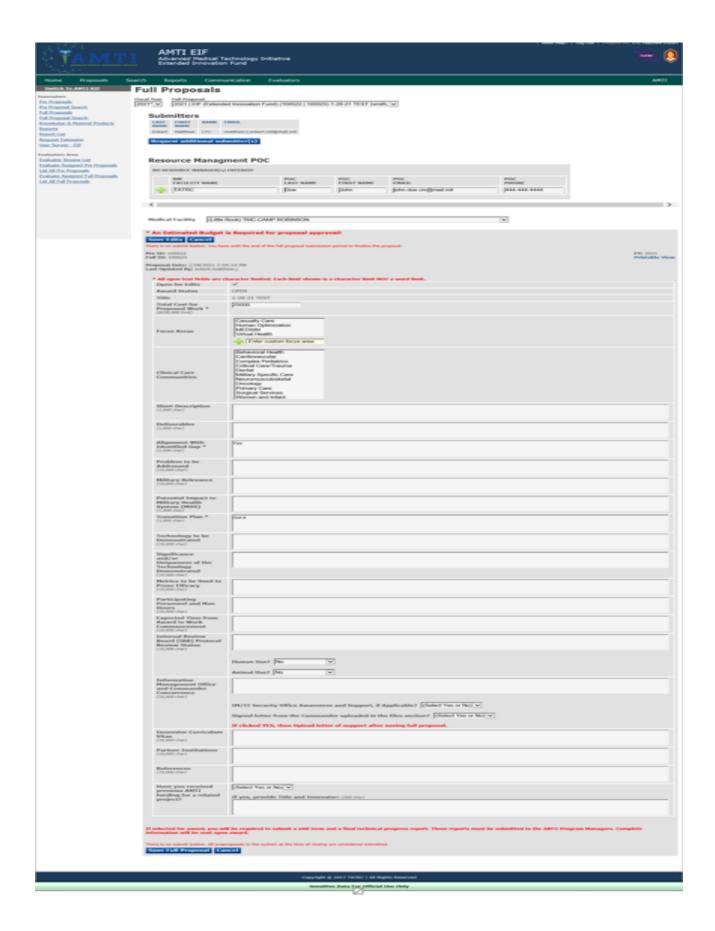
Upon review of the Preproposals by a peer review panel, Preproposals that merit further exploration will be invited for further consideration via the submission of a Full Proposal. Preproposals are rated and based on the following criteria: innovative concept, military relevance, metrics for success and potential return on investment. Full Proposal submission is by invitation only. All Preproposals will be assigned an identification number after receipt. Evaluations will be held for 60 days and then Invitations will be sent out for Full Proposal submissions. Once created, proposals will be listed as open. If the proposal becomes an awarded proposal, the status of the proposal will change to Awarded. If it is rejected the status will change to rejected.

# Preproposal Template for Extended Innovation Funding (EIF)

Each Preproposal created must first identify the title and medical facility. If content is pasted from Word, it will require adjustments as the system utilizes an ASCII format in the online submission system.

Once the title, medical facility, cost, submission type, medical facility, alignment with identified gap and transition plan are identified then the rest of the preproposal template can be populated. If there is no identifiable gap state the gap has not be identified yet. For the transition plan, state the long term goal if the project is successful and what unit, agency and/or organization would manage it.





# **Explanation of EIF Preproposal Entry Fields**

#### Preproposal Extended Innovation Fund (EIF) Program Template

**Title:** (*Limit to 250 characters*)

Innovator: (Last Name, First Name, Rank, Email, Title, Corps, Address Phone, Facility, Lead,

Active)

Additional Innovators: (Last Name, First Name, Rank, Email, Title, Corps, Address Phone,

Facility, Lead, Active)

Medical Facility: (Chose from the drop down menu)

Focus Areas: (Choose from the drop down menu)

Clinical Care Communities: (Chose from the drown down menu

**Cost:** Do not use commas or decimal points only enter numerical values.

**Short Description [***Abstract***] (1,000 character limit):** There are character limits. If you have typed too many characters, you will receive an error message and you will not be able to submit the proposal. If this happens you will need to start editing the entered text until it contains the acceptable number of characters. DO NOT USE THE FOLLOWING SYMBOLS < OR >. If your text contains those symbols you will see an error appear in red; you then must delete the symbols and type out "less than" or "greater than" respectively.

**Deliverables (1,000 character limit)**: What is the purpose of this project and what will be the final deliverables? Provide CONOPS - to include skillsets, specific personnel, program process, sites to be included, etc. Identify the significant milestones that must be met (IMIT issues, approvals for content and access, etc.). Identify the benefit in terms of impact on Cost, Access, and Quality of Care (if applicable).

Alignment with Identified Gap (1,000 character limit): Your project should be in strategic alignment with current leadership guidance on gaps that need to be filled for the future of military medicine. Please reference any identified gaps. If an overarching gap cannot be identified, then state how you came to the conclusion that there was a gap in services, technology or process at the local level that needs to be filled.

**Problem being addressed including references (10,000 character limit):** What is the problem you are trying to solve (to include prevalence and severity)?

**Military Relevance (10,000 character limit):** How will the military benefit, what military requirements does it address? Does it impact Graduate Health Science Education?

Potential Impact to the Military Health System (MHS) (1,000 character limit): What is the future impact if this project is successful to the local facility and MHS as whole? Could this project be expanded? Could this project be picked up as an enterprise-wide solution? Would this be appropriate at all MHS sites? What value would it bring to the MHS in terms of cost savings, improvements in safety, efficiency, efficacy or readiness?

**Transition Plan (1,000 character limit):** If this project proves to be beneficial, has a transition partner been identified that could take the project on and transition it to a program of record? What would be the next steps after this initial project? (e.g. A randomized clinical research study, stage deployment at multiple sites.)

Methods (to include Human/Animal Use) (10,000 character limit): What clinical investigations office will be utilized? Is a protocol already developed?

**Description of Metrics / Outcome Measures (10,000 character limit):** How do you intend to measure the success of the proposed demonstrations? What criteria will be used and how will the data be measured, verified and analyzed?

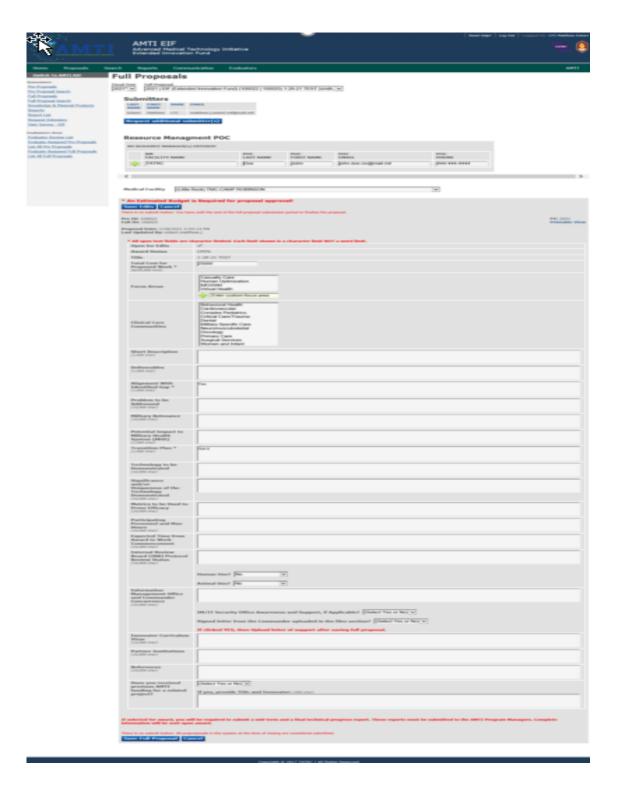
Infrastructure, Equipment, Personnel and Subjects Needed (10,000 character limit): Name, Title, Role, Effort (%). Note: Military and Civilian personnel should be identified as part of the proposed effort in this section but their salaries cannot be part of the budget.

Partner Institutions (10,000 character limit): List all partners and their role in the project.

# **AMTI EIF Full Proposal Submission Process**

Upon invitation email Innovators may submit a full proposal for consideration.

# Full Proposal Template for the Extended Innovation Funding (EIF):



### **Explanation of EIF Full Proposal Entry Fields**

#### **Full Proposal Template**

Total Cost for Proposal Work: \$250,000 limit

**Short Description (1,000 character limit):** There are character limits for each section. If you have typed too many characters, you will receive an error message and you will not be able to submit the proposal. If this happens, you will need to start editing the entered text until it contains the acceptable number of characters. NOTE: DO NOT USE THE SYMBOLS < OR >. If your text contains those symbols you will see an error appear in red; you then must delete the symbols and type out "less than" or "greater than" respectively. Spaces count towards character limits. This section should give an executive summary of your proposed project.

**Deliverables (1,000 character limit)** What is the purpose of this project and what will be the final deliverables? Provide CONOPS - to include skillsets, specific personnel, program process, sites to be included, etc. Identify the significant milestones that must be met (IMIT issues, approvals for content and access, etc.). Identify the benefit in terms of impact on Cost, Access, and Quality of Care (if applicable).

Alignment with Identified Gap (1,000 character limit): The proposed project should be in strategic alignment with current leadership guidance on gaps that need to be filled for the future of military medicine. Please reference any identified gaps. If an overarching gap cannot be identified, then state how you came to the conclusion that there was a gap in services, technology or process at the local level that needs to be filled.

**Problem to be addressed (10,000 character limit):** What is the problem you are trying to solve (to include prevalence and severity)?

**Military Relevance (10,000 character limit):** How will the military benefit? What military requirements does it address? Does it impact Graduate Health Science Education?

Potential Impact to the Military Health System (MHS) (1,000 character limit): What is the future impact if this project is successful to the local facility and MHS as whole? Could this project be expanded? Could this project be picked up as an enterprise-wide solution? Would this be appropriate at all MHS sites? What value would it bring to the MHS in terms of cost savings, improvements in safety, efficiency, efficacy or readiness?

**Transition Plan\* (1,000 character limit):** If this project proves to be beneficial, has a transition partner been identified that could take the project on and transition it to a program of record? What would be the next steps after this initial project? (For example: a randomized clinical research study or a staged deployment at multiple sites.)

**Technology/Process to be Demonstrated (10,000 character limit):** What is the technology or process that will be utilized as part of the proposed project.

Significance and/or Uniqueness of the Technology/Process Demonstrated (10,000 character limit): Provide a literature review of this technology/process, references should be listed in the references section. Describe how it might currently be utilized in the civilian sector as well as within the military. Explain how this demonstration/study builds upon previous work or fills an existing identified gap in capability or knowledge. Describe how the project is in alignment with current strategic priorities within the MHS. If this is a follow on effort to a previous effort list how this proposed project advances the technology/process beyond the original effort.

Metrics to be Used to Prove Efficacy (10,000 character limit): How do you intend to measure the success of the proposed demonstration? What criteria will be used and how will the data be measured, verified and analyzed?

Participating Personnel and Man Hours (10,000 character limit): Provide Name, Title, Role, Organization, Effort (%), and contact information including phone and email for each person that will participate in the effort even if they are not going to be included in the budget. Military and civilians should be listed but their costs cannot be included as part of the budget. If personnel will not be hired until after funds have been received, identify the position and label it with TBA (to be announced).

**Expected Time from Award to Work Commencement (10,000 character limit):** When will you be able to start once funds are provided? Will any contracts have to be developed to support this project? Detail any personnel support that may be in place already to support this project. Will the project require IRB/IACUC approval and which institution will be utilized? Do not list any specific personnel, vendors or products by name to avoid conflicts of interest with any contracts that may need to be created.

Institutional Review Board (IRB)/Institutional Animal Care and Use Committee (IACUC) Protocol Review Status (10,000 character limit): What are the human or animal use issues attendant to this project? Any proposal that requires interactions with humans or animals is required to have a research determination from their local IRB/IACUC. Show that you are aware of, and are prepared to address, any human/animal use issues as part of your IRB/IACUC approval requirement. Specifically list the clinical investigations office you will be utilizing if IRB/IACUC approval is required. Use the dropdown menu to identify whether or not there will be human or animal use.

Information Management Office (IMO) and Commander Concurrence (10,000 character limit): Have you engaged the IMO and Commander's office regarding the proposal? Has the local IMO confirmed that the technical infrastructure exists to allow for success for completion of this project? Is your chain of command aware of the project and its time requirements should you be funded? Use the dropdown menu to select Yes or No. Letters of support should be uploaded in the files section of your proposal. They should be signed and from your IMO, Commander and any relevant Consultant(s) or Service Line Support. These should be uploaded after saving full proposal. Identify that there are letters of support requiring review by selecting yes in the filed "Departmental and Command Support".

**Innovator Curriculum Vitae (10,000 character limit or 1 page limit):** Please abbreviate CV content so that it relevant to this individual submission. This should be for the lead Innovator.

Partner Institutions (10,000 character limit or 1 page limit): List all partners and their role in the project.

**References (10,000 character limit):** List all references, sources utilized to build this proposal and explore the technology/process.

Have you received previous AMTI funding for a related project? (500 character limit): Select Yes or No from the dropdown. If yes, provide the title and PI name. Acknowledgement allows for tracking of progression of a concept and does not negatively impact selection.

Click on the "Save Full Proposal" button. It will take you back to the top of the screen where you now must complete the budget.

Once you click the "Save Full Proposal" button you should see a pop up "Alert" that reads "You have successfully started your Full Proposal! You must now complete the following:

- [1] Finish filling in the Full Proposal details.
- [2] Enter an Estimated Budget

Click on the "OK" button to proceed.

**Resource Management POC (Please complete ALL information).** AMTI funding is DHP O&M and can ONLY be sent to a Facility Resource Management office. List a military or government POC who can accept the funds and assist the PI in execution of the funding. To add additional contacts, click on the green arrow and populate each module. Funding CANNOT be sent to a contracting agency, it can only be sent to a Military Treatment Facility Resource Management Office.

### Click on the "Estimated Budget" button.

Military and civilian salaries should not be included in the budget, but contractor salaries can be submitted. Travel for Military and Civilians can be listed in the budget, but it must be completed the year AMTI funding is received. Travel for contractors can be included and put on the ODCs for their contracts. Indirect fees should be built into other costs and not separated out. Submitters are encouraged to work with their Resource Management office early and often to ensure proper coordination and timely execution of funding should the project be awarded funding. The AMTI does not fund preparation of submissions.

Populate each module and click the "Add Labor Item". Note you can correct a line item by clicking on the "pencil" or you may delete an item by clicking on the "trash can". By clicking on the green "+" sign you may add additional items. Continue this same process for the "TOTAL MATERIALS" section. In the "Travel" section, populate each module with appropriate information and click on the "Add Travel Item" button.

Follow this same process for each trip. Continue this same process for the "TOTAL DIRECT COSTS" section.

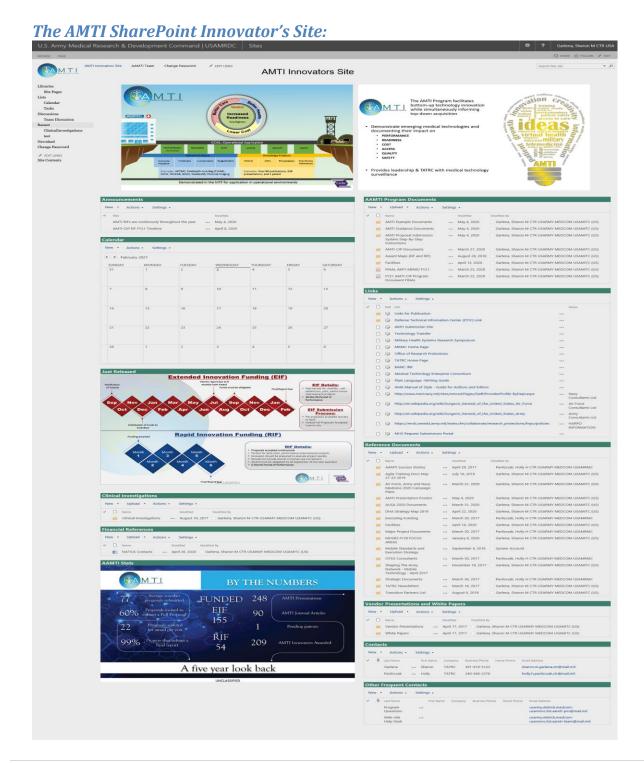
Once you've completed all of the budget modules and are satisfied, click on ID to return to Proposal link, which will take you back to your proposal. A fully populated full proposal should appear.

Scroll down to the bottom of the Full Proposal to upload any other relative documents (i.e., IM/IT Security Office Awareness and Support, if applicable, Departmental and Command Support, Relevant Consultant or Service Line Support, etc.) you wish to include with your submission, click on the "File Upload" "Browse" button. Locate your documents on your computer. Once located, click on the document and then click on the "Open" button. You should see the link appear in the "File Upload" module.

Next click on the "Upload" button and your document will appear under the "Files" module. Repeat these steps for each document you wish to upload with your proposal submission.

### **AMTI SharePoint Site**

The AMTI SharePoint site is open to potential and previous AMTI Innovators with CAC access and a milnet computer and access will be granted at the time of the initial AMTI account is established. The site provides access to timelines, reference documentation and templates that may be helpful to Innovators. Access to the site is automatic and simultaneously initiated at the same time as an AMTI Proposal Submission System account is setup. Once an AMTI Proposal Submission System account is setup Innovators will receive a second email notifying that their access is approved for the AMTI SharePoint site at <a href="https://mrdc-partners.amedd.army.mil/sites/AAMTI/">https://mrdc-partners.amedd.army.mil/sites/AAMTI/</a>.



### **Evaluation Process**

### **RIF Evaluation Process**

AMTI RIF Proposals are reviewed by TATRC Leadership and Peer Review Subject Matter Experts (SMEs). They are evaluated with same focus criteria as AMTI EIFs: Innovative Concept, Military Relevance, Metrics, and Potential Return on Investment.

### **EIF Evaluation Process**

There are two phases in the EIF evaluation process Preproposal and Full Proposal evaluation.

### EIF Preproposal Evaluation Process

The EIF Evaluation Process has two phases preproposal and full proposal. Peers are selected to serve on a preproposal evaluation board. Each proposal is evaluated based on the following criteria: Innovative Concept, Military Relevance, Metrics and Potential Return on Investment. Each preproposal is given a score of 1-25 in each evaluation criteria and evaluators are encouraged to provide comments that would assist Innovators in shaping their proposal should it be selected for the full proposal phase. Comments from preproposal reviewers are available as a link in the notification email that is sent out as part of award notifications. The comments are also available any time within the AMTI Proposal Submission System on the proposal submission page at the top right hand side labeled "comments" in blue.

Preproposal reviewers are not responsible for evaluating budget, the emphasis is on the concept.

Create New Pre Proposal Edit this Pre Proposal

ID: 8519
Submitter(s): Pavliscsak, Holly Review Comments
Proposal Date: 1/8/2018 8:43:40 AM
Last Modified By: pavliscsak.holly.hardison.1296757299

An evaluation board in combination with the TATRC Director make the final decision on the preproposals that will receive full proposal invitations.

FULL Proposals are **REQUIRED** to have a letter of concurrence from their local COMMANDER prior to submission. A letter from a clinical community subject matter expert (SME) and department head in the project subject area are also recommended.

Awards are dependent upon adequate demonstration by the Innovator that they have considered administrative issues related to interfaces with legacy systems or enterprise solutions (existing and planned), research involving/anatomical substances including cadavers, research using survey or other information solicitation instruments, research involving animals, Facility Safety Plan (FSP), and Certificate of Environmental Compliance. As a consequence, awardees should initiate IRB/IACUC/DHA procedures in accordance with their local command authority standard operating procedures at their earliest convenience. Once IRB/IACUC/DHA determination is made Innovators are free to start.

# **EIF Full Proposal Evaluation Process**

AMTI Innovators who are selected for full proposal will receive an email notice of invitation to submit proposal. They will then have approximately 6 weeks to submit a full proposal for consideration. Full proposals should fully address any issues that have been brought up by the Preproposal reviewers. AMTI Full Proposals will be evaluated by a separate group of Full Proposal Reviewers. They will evaluate the proposals on the following criteria Innovative Concept, Military Relevance, Metrics and Potential Return on Investment. Each proposal is given a score of 1-25 in each evaluation criteria and evaluators are encouraged to provide comments. Full proposal reviewers also evaluate the qualifications of the Innovator and facility, feasibility of the budget and timeline and validity of letters of support. Proposals are then evaluated in a group setting to discuss the merits of each proposal and a list of recommended proposals is then presented to the TATRC Commander for award selection. Comments from full proposal reviewers are available as a link in the notification email that is sent out as part of award notifications.

The comments are also available any time within the AMTI Proposal Submission System on the proposal submission page at the top right hand side labeled "comments" in blue.



### **Award Process**

AMTI EIF Awards are made in September each year. AMTI RIF awards are reviewed and funded based on funding availability year round. The timeframe for the award is listed on the top left hand side of each proposal in the AMTI Proposal Submission System. Notifications are sent out via email with instructions on next steps. The AMTI Call for Proposals is funded with DHP O&M funds. This is one year money that must be obligated by 30 September in the fiscal year in which funds were transferred. Funding is sent to the local facility or to partner contracting agency for execution. The facility and Lead Innovator are responsible for the obligation and management of the funds once transferred. Once notified of award, Innovators must attend a kick off meeting with the AMTI PM to go over the requirements for the award. Innovators are responsible for the fiscal, administrative and clinical investigations execution of their projects once funding is transferred. These funds are NOT GRANTS, they are awards to complete a specific demonstration project.

Prior to funds distribution, the Commander and Resource Management Office (RMO) at Military Treatment Facility (MTF) or Operational Unit (OU) will be required to complete and sign a support agreement in accordance with DOD INSTRUCTION 4000.19 on Fiscal Service (FS) Form 7600A, "Interagency Agreement (IAA) — Agreement Between Federal Agencies General Terms and Conditions (GT&C) Section," located at https://www.fiscal.treasury.gov/g-invoice/resources.html#admin. AMTI funds are transferred to the Innovator assigned organization's RMO via MIPR/FAD to the resource management office.

AMTI will accept Navy and Air Force applications but has no guarantee of funding from these services yet.

AMTI funding is DHP O&M and OMA funding and must be executed in the year of award.

Government travel for military and civilian staff must be completed before 30 September of the issuing year. Contractors may put that funding on their contract ODCs. As a reminder, AMTI funding should not be utilized for projects more appropriately funded with RDT&E funding such as drug/device trials. It is the responsibility of the Innovator and the receiving RMO to place the funds on contract(s) and complete all activities necessary to create, manage and execute the contract. Innovators must provide their desired method of distribution of funds to include your RMO Point of Contact (POC), amount of funds that should be sent to your local RMO office. In order to facilitate the execution of AMTI funds, contact must be made with contracting early to determine their ability to place all funds on contract(s) in a timely manner.

The AMTI funds can be utilized to support contract support to assist in execution of the AMTI proposal. Once funding is sent to your local RMO office, they can send the funds to their identified contracting agency. Innovators can also use their local contract office to develop any necessary contracts Local RMOs usually handle travel and small credit card purchases for the AMTI projects. Contracting can be contacted prior to proposal submission for guidance on the contracting process and contracting options to support AMTI projects.

Contracts for AMTI projects generally involve support personnel and advanced technology purchases to complete small short-term demonstration projects. This program is designed to foster and encourage new projects that reflect "medical technology entrepreneurship". Acquisition efforts are not eligible for this program and will not be considered. Funded projects are 6 months (RIF) to 18 months (EIF) respectively for execution, therefore, infrastructure, equipment, personnel, etc. should be obtainable in a reasonable amount of time from the award date.

# **Innovator's Responsibility**

Before funds are distributed Innovator's must acknowledge Innovator's Responsibility:

The Innovator will bear primary responsibility for the conduct of the project and will exercise judgment towards attaining the stated project objectives.

The Innovator specified in the funding document will be continuously responsible for the conduct of the project and will be closely involved with the effort. In the event the Innovator is changed, for whatever reason, the AMTI Program Manager must be notified so that the change in Innovator is made in the AMTI Proposal Submission System identifying the new Innovator and contact information. Furthermore, a Curriculum Vitae must be provided to the AMTI Program Manager for review prior to replacement. Any identified Innovator needs to be at the facility that receives the funds to manage the funding and must be a civilian or military assigned to that facility. Awards are made to facilities not individuals and the funding does not transfer in the event of a move by the Innovator to a new location. You may recommend a Submitter be established for this project in the AMTI Proposal Submission System. The Submitter must have an active CAC and milnet computer to obtain an AMTI Proposal Submission System account, which will allow them to provide administrative support to include uploading any required documentation and will receive notifications of deadlines and requirements to include the notification and coordination of any publications, patents, awards and/or presentations that may result from the original award. All correspondence should have the full proposal ID number, proposal award number, title and Innovator name.

# **Publication and Acknowledgment**

The Innovator is encouraged to publish and present results of the project, unless classified, in appropriate journals. The Innovator must provide a copy of the proposed effort for the AMTI Program Manager review and include the following appropriate funding acknowledgment in any presentations, publications, or other public descriptions of the project and/or its results, "This work was funded by the Telemedicine and Advanced Technology Research Center (TATRC) at the United States Army Medical Research and Development Command through the Advanced Medical Technology Initiative (AMTI). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army." Copies of all publications resulting from the work must be submitted through the AMTI Proposal Submission System via the Knowledge & Material Products module.

# **Knowledge and Materials**

Recording the knowledge products directly in the AMTI system from AMTI projects is required for the long-term justification of the program. Knowledge products include: publications, peer review articles/papers, manuscripts and abstracts, conference papers, presentations, posters, study questionnaires, surveys, program of record establishment and/or patent applications that result from an AMTI project either during the project timeline or after the completion of the project. There is a section for entry of any knowledge or material products produced from your

project in the AMTI Proposal Submission System. Awardees will be sent reminders for three years after the conclusion of their project to report any knowledge and material products that may be generated as resulted of the funded work.

### **Public Releases**

Prior to release to the public, the recipient shall notify the AMTI Program Manager, Telemedicine and Advanced Technology Research Center (TATRC) of the following: planned news releases, planned publicity, and advertising material concerning the project and planned presentations to scientific meetings. This provision is not intended to restrict dissemination of information; the purpose is to inform the leadership including the Defense Health Agency and/or U.S. Army Medical Research and Development Command (USAMRDC) of planned public release of information, in order to adequately respond to inquiries and to be alerted to the possibility of inadvertent release of information, which could be taken out of context. Any publication of information or research results, however, should be consistent with applicable DOD and Service confidentiality statues and regulations as well as MEDCOM/BUMED/AFMS policy and the Privacy Act 5 U.S.C. 552a. All correspondence should have full proposal ID number, title and Innovator name.

### **Information Release**

Statement (a.) shall be included in all such releases for any publications or presentations; Statements (b.)-(e.) shall be included if relevant to the project being conducted:

- a. For AMTI: "This work was funded by the Telemedicine and Advanced Technology Research Center (TATRC) at the United States Army Medical Research and Development Command through the Advanced Medical Technology Initiative (AMTI). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army."
- b. "In conducting projects using animals, the innovator(s) adheres to the laws of the United States and regulations of the Department of Agriculture."
- c. "In conducting projects using humans and/or human anatomical substances, the innovator is required to include approvals, forms, and descriptions."
- d. "Information" includes, and is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings and symposia.
- e. "This work was funded by the Advanced Medical Technology Initiative (AMTI), through the Telemedicine and Advanced Technology Research Center (TATRC)".

# **Financial Update Information**

The Innovator will be responsible for creating a financial record update for their AMTI project to provide visibility and transparency on the funding expenditures toward the project in the Financial section in the AMTI system. Your actual budget will likely be different from your originally estimated budget. Please just enter what you spent the funding on and the justification surrounding any difference in the estimated costs. A request for a financial report will be sent out in October of the year of award.

# **Technical Reporting Requirements**

The final report shall be submitted no later than 6 months for RIFs and 18 months for EIFs from the date funds are sent to the receiving organization and must be submitted according to the guidelines below. Innovators who do not complete reporting requirements in a timely fashion will not be allowed to apply for additional AMTI awards.

### Format Requirements for Final Reports

A final report summarizing the entire award effort and providing a complete reporting of the project findings must be submitted. Journal publications cannot be substituted for any part of the final report, but may be referenced in the text. The final report will be submitted electronically using a template that will be available in the email reminder that will be sent forward. All final reports should be submitted directly into the AMTI Proposal Submission System through the link provided in the reminder email.

A Quad Chart must also be submitted at the time of final report entry and we are excited to rollout an easier way for you, our AMTI users, to generate your final quad chart. The final quad chart will now be automatically generated within the AMTI system. Please access the step-by-steps at the AMTI SharePoint page before inputting your final quad chart directly into the AMTI system for submission.

Projects that need to transition should be submitted to the following site for formal vetting and funding: <a href="https://info.health.mil/sites/MHSRSP/LIVE/SitePages/Home.html">https://info.health.mil/sites/MHSRSP/LIVE/SitePages/Home.html</a>

# **Presentation of Findings**

Upon the completion of the project or the program deadline, the Innovator or a project representative, may be invited to present the final results from the work at a TATRC event or the Military Health Services Research Symposium. The date, time, location, and format for the presentation will be announced at a later date.

# **Use of Human or Animal Subjects**

The Innovator, or its co-Innovators, shall not conduct any human or animal research, or enroll any human subjects under this award until the protocol(s) has been reviewed and approved by the appropriate institutional review board at the Innovator's location, if required.

# **Obligation of Funds**

Funding for this project is DHP O&M or OMA one year money. Although the recipient has six months for RIFs and eighteen months for EIFs to complete the work, all funds must be obligated by 30 September of the year funded. Any funds not obligated by 30 September should be returned and will no longer be available to the original recipient. The Innovator is advised to coordinate with the resource management and contracting authority to ensure that all contracting requirements are established in a timely fashion. Familiarity of, and compliance with, all contracting requirements, including all applicable acquisition regulations, is the responsibility of the Innovator. Permissions to execute the project at the local facility are the responsibility of the Innovator. Because of the volatile nature of the budgeting process, you are advised not to engage in any activity that obligates funds, or promises to obligate funds, until such time as project funds are MIPR'd or FAD'd to your facility.

# **Freedom of Information Act Requests**

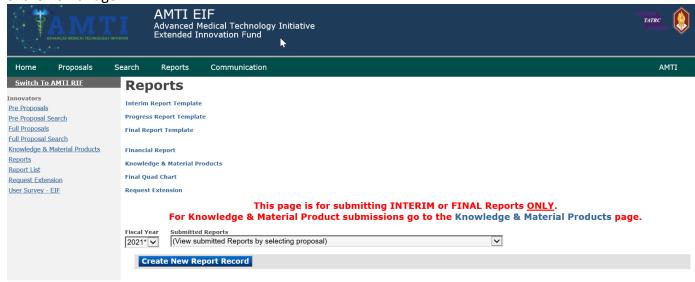
The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official Government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (<a href="http://www.aclu.org/library/foia.html">http://www.aclu.org/library/foia.html</a>). When a FOIA request asks for information contained in a successful Submission that has been incorporated into an award document, the Submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by the appropriate DoD agency in making its final determination concerning which information is or is not releasable. If information requested is releasable, the Submitter will be given notice of DoD's intent to release and will be provided a reasonable opportunity to assert available action.

### **Report Process**

TATRC monitors the progress of funded projects throughout execution. Reports should be submitted electronically via the AMTI Proposal Submission System. Email reports will not be accepted. Report templates are available at the report submission page as well as on the main AMTI homepage and the SharePoint Portal. Examples of past reports can also be found on the AMTI SharePoint portal. An individual reporting schedule will be developed for each project. Each innovator will work with the AMTI Portfolio Manager to develop a reporting schedule for the progress, interim and final reports. EIF Reports are due at 9 months (interim) and 18 months (final) and each RIF requires a final report at 6 months.

Innovators will be notified 90, 60, 30 days before a report due date and 30, 60, 90 days after a report due date via email with a link directly to the reporting section of the AMTI Proposal Submission System. An E-book of QUAD charts are available for leadership at the end of each year, highlighting the projects that were funded. The final results may be presented at an exhibition at a time and location to be determined.

The report templates can be found in the reminder email that will be sent when reports are due, the AMTI Home Page (<a href="https://tatrc.amedd.army.mil/AMTI/Default.aspx">https://tatrc.amedd.army.mil/AMTI/Default.aspx</a>), as well as the report submission page within the AMTI Proposal Submission System and on the AMTI Innovator's Share Point Page.



Fiscal Report: Once funding is issued the information on contracts to complete the work will be required by the AMTI Portfolio Manager. Monthly reporting on the distributions of funds will be assessed by the TATRC Resource Management Office (RMO). These reports will be requested by TATRC's RMO and will be entered in the financials section of the AMTI Proposal Submission System. Both EIF and RIF projects will be required to complete a fiscal report. By the end of the fiscal year in which funds are received awardees are required to enter their actual final expenditures into the AMTI Proposal Submission System in the Financial Report section. They should also upload any associated documentation such as market research, contracts, etc.

Interim Report: The interim report shall provide a brief, factual, and informal overview (positive or negative) of the project. The report is due halfway through the project, which is approximately nine months from the date of funding. Only required for EIF projects. NOTE: Interim reports are not eligible for an extension because they are an administrative update only.

Final Report: The final report shall provide a complete summary of the results (positive or negative). The report shall be of sufficient length to provide a thorough description of the work including accomplishments and future initiatives. The report is due at the completion of the project, which is approximately 6 months for RIF and 18 months for EIF from the date funding is received. A QUAD chart is required at final report.

[Optional] Progress: At the discretion of the AMTI Portfolio Manager, a progress update may be requested. The progress update shall provide a brief, factual, and informal overview (positive and negative) of the project. The update will typically be requested between the interim and final report, and submitted in a timely manner to the Program Manager.

Progress Report may be required if reporting is delayed for both funding mechanisms (EIF and RIF).

[Optional] Final Presentation may be made by the Innovator at an open house event and place to be determined. This presentation (if scheduled) would typically occur in the calendar year following the obligation date of project funds, thus each funded Activity will be responsible for all costs associated with the final presentation.

The AMTI Portfolio Manager may visit each Innovator during the project lifecycle. All visits will be coordinated ahead of time.

### **Request for Extension**

If there is an issue with contracting, clinical investigations, Innovator ability or another unforeseen delay to execute the project, Innovators may submit an extension request. There are two extensions that need/may need to be sought if a project is behind schedule. One is administrative approval that is done through the AMTI Proposal Submission System. The other approval that needs to be obtained is through the contracting office for any contracts that are supporting the proposal. Innovators can seek a no cost extension through contracting but they must still submit an administrative extension through the AMTI Proposal Submission System. Approval is based on the AMTI Portfolio Manager's discretion. Request for extensions must be System submitted into the AMTI Proposal Submission at https://tatrc.amedd.army.mil/AMTI/Default.aspx.

NOTE: Updating the month calculation based on current date; if the current date is less than or equal to the due date – no change. Otherwise, new date is month requested plus current date.

