Request for Project Proposals

Solicitation Number: AFIRM 001

**"Armed Forces Institute of Regenerative Medicine (AFIRM)
Fiscal Year 2024 (FY24) Clinical Trial Award"**

Issued by:
Wake Forest Institute for Regenerative Medicine
The AFIRM Coordinating Center

Request Issue Date: March 28, 2024

White Paper Due Date: April 30, 2024
Noon Eastern Time

Anticipated Full Proposal Invitation Date: June 4, 2024

Full Proposal Due Date: To Be Determined

Award Notice Date: To Be Determined

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1 Executive Summary

1.1 The Armed Forces Institute of Regenerative Medicine

The Department of Defense (DoD) established the Armed Forces Institute of Regenerative Medicine (AFIRM) to provide measurable acceleration of regenerative medicine clinical product transitions. The vision of the AFIRM is to develop therapeutic strategies to return wounded and injured Service Members to full form and function. The overall AFIRM program is to develop and deliver impactful advances in health care of Service Members, Veterans, and Beneficiaries, and by extension, the American public.

The AFIRM Consortium offers experienced management across multiple leading research institutions, industry and government partners currently working on DoD relevant regenerative medicine technologies. Consortium partnerships have also been established with other relevant stakeholders, including foundations, and regulatory, manufacturing, financial and commercialization entities, all with deep expertise in the regenerative medicine space. This partnership network provides a means to accelerate the clinical translation of critical regenerative medicine technologies into commercial products for the treatment of battlefield injuries of greatest concern to the DoD.

1.2 Purpose

This solicitation is issued by the Wake Forest Institute for Regenerative Medicine (WFIRM) as the AFIRM Coordinating Center (CC). WFIRM serves as the AFIRM execution management agent through Other Transactions Authority (OTA) award MTEC-23-04-AFIRM-004 issued by the Medical Technology Enterprise Consortium (MTEC). Program priorities, award decisions, and oversight are the responsibility of the Combat Casualty Care Research Program (CCCRP) and the U.S. Army Medical Research Acquisition Activity (USAMRAA), both part of the U.S. Army Medical Research and Development Command (USAMRDC). The AFIRM program and AFIRM CC are responsible to the MTEC and to the CCCRP for program execution.

This Request for Project Proposals (RPP) is focused on supporting regenerative medicine clinical trials to improve prevention, detection, diagnosis, treatment, and/or quality of life. Awards made from this effort are intended to support a clinical trial having FDA approval, an FDA exemption, or for overseas trials – host nation regulatory approval, preferably at the time of application submission but no later than 90 days after the award is made; the clinical trial is expected to begin no later than 6 months after the award date.

2 Administrative Overview

2.1 Acquisition Approach

This RPP will be conducted using a White Paper approach. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for Offerors.

- **Stage 1:** White Papers submitted under this RPP shall follow the White Paper Template provided in **Section 8.** The AFIRM CC and the Government will evaluate White Papers submitted and will select White Papers that best meet their current technology priorities using the criteria in Section 5 of this RPP.

- **Stage 2:** Offerors whose solutions are selected for further consideration based on White Paper evaluation will be invited to submit a Full Proposal in Stage 2. Documents anticipated to be needed for Stage 2 submissions can be found in Section 3 of this RPP. Notification letters will contain formal Stage 2 proposal submission requirements.

- NOTE: Invitation to submit a full proposal is based on the contents of the White Paper, and therefore, investigators should not change the title or research objectives after the White Paper is submitted. The applicant organization and associated PI identified in the White Paper should be the same as those intended for the subsequent full application submission. **A change in research objectives, PI, or organization will likely result in withdrawal of the full proposal invitation, the full proposal will not be reviewed, and/or recission of an award notification, if one has been made.**

White Papers will not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page.

The prototype project(s) selected as a result of this solicitation are expected to be included as subcontractors under the MTEC-23-04-AFIRM-004 OTA award and will work with AFIRM CC, CCCRP, MTEC, and USAMRAA to finalize their inclusion into that award.

2.2 Funding Availability and Period of Performance

The U.S. Government (USG) currently has available approximately $10 million (M) for this effort. Offerors are not restricted to a predetermined cost limit. However, Clinical Trial Award (CTA) proposals are expected to be in the range of $1-5 M in total (direct and indirect) cost. Dependent on the results and deliverables under any resultant award(s), the USG may, non-competitively, award additional dollars and/or allow for additional time for scope increases and/or follow-on efforts with appropriate modification of the award. Additional funds may also become available to fund new CTA projects or to expand selected/funded CTA projects within the AFIRM.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

The AFIRM CC expects to make **multiple awards** to qualified Offerors to accomplish the scope of work. If a single proposal is unable to sufficiently address a Focus Area of the RPP, several Offerors may be asked to work together in a collaborative manner.

Offerors should plan on the period of performance beginning September 2024 (subject to change). The AFIRM CC and the Government reserve the right to change the proposed period of performance start date through negotiations via the CC and prior to issuing awards. The Period of Performance is not to exceed **4 years**. Awarded funds must be expended by 23 December 2028. No-cost extensions will NOT be allowed.

2.3 Proprietary Information

The AFIRM CC will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The AFIRM CC shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. **Please mark all Confidential or Proprietary information as such.** An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CC responsibilities.

2.4 Offeror Eligibility

All U.S. organizations, including academia, industry, and non-profits, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs. Government agencies must provide details on how AFIRM CTA funding will be received and managed.

Foreign organizations, foreign public entities, and international organizations are eligible to apply. Foreign institutions must provide details on how AFIRM CTA funding will be received and managed.

The AFIRM CC makes subawards to eligible organizations, not to individuals.

Principal Investigator (PI): Investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the PI on the application.

Each investigator may be named on only one FY24 AFIRM CTA application as a PI.

MTEC membership is not required for submission of a white paper. If interested in joining MTEC, please visit http://mtec-sc.org/how-to-join/.

At the time of the submission, if Offerors have not yet executed an MTEC Base Agreement, then Offerors must certify on the cover page of their Proposal that, if selected for an award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement **(https://mtec-sc.org/documents-library/).** If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Proposal that, if selected for an award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

2.5 Cost Sharing

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). Cost sharing is not required to be eligible to be selected for award under this RPP. Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind

contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

2.6 Assessment Fee

Offerors selected for funding under the AFIRM FY24 CTA program are expected to become sub-contractors to the AFIRM CC (WFIRM) per MTEC-23-04-AFIRM-004. Funded Offerors will be assessed a 2% award fee at the start of each year of planned research funding as this fee is a requirement within the base MTEC-23-04-AFRIM-004 agreement. This fee is not chargeable as either a direct or indirect cost for reimbursement from the CTA. The assessment fee is also not chargeable to another federal grant or contract.

2.7 Intellectual Property and Data Rights

It is anticipated that anything created under this proposed effort would be delivered to the USG with Government Purpose Rights or Unlimited Data Rights unless otherwise asserted in the proposal and agreed to by the Government.

Note that as part of Stage 2 of the RPP process (submission of an invited full proposal), Offerors shall provide more information on Intellectual Property and Data Rights with the Signature of the responsible party for the proposing Offeror.

2.8 Expected Award Date

The expected award date is to be determined.

2.9 Anticipated White Paper Selection Notification

As the basis of selections is completed, the CCCRP will forward its selection(s) to the AFIRM CC to notify Offerors. All Proposers will be notified by email from the AFIRM CC of the results of the evaluation. Those successful will move forward to the next stage of the process – full proposal submission.

Offerors are hereby notified that once a White Paper has been submitted, neither the Government nor the AFIRM CC will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 Technical Requirements

3.1 Background

The DOD first established the AFIRM in 2008 in the form of two consortia, one led by Wake Forest and the other by Rutgers University. A second solicitation for AFIRM in FY13 (AFIRM II) resulted in an award to a single consortium, led by Wake Forest. A non-Consortium solicitation for AFIRM in FY19 provided funding to partnering project awardees focused on a narrower technical scope which included only peripheral nerve regeneration and skeletal muscle regeneration. The current AFIRM consortium program was solicited through the MTEC under RPP# 23-04-AFIRM, which resulted in an award to the WFIRM as the CC.

The current AFIRM CC (WFIRM) is expected to facilitate development and translation of regenerative medicine technologies related to Warfighter needs. The intent is to transition several regenerative medicine products to the Warfighter and the commercial marketplace. Due to the specialized expertise of the WFIRM team, this approach will de-risk technology development by providing capability/expertise to companies that have promising technologies.

Additionally, the AFIRM CC works closely with the CCCRP in an actively coordinated effort to address the regenerative medicine needs of the DoD. This allows the AFIRM CC to:

- Assist in the identification and prioritization of regenerative medicine technology of relevance to the DoD,
- Provide recommendations to CCCRP for the allocation of funding,
- Support MTEC and CCCRP by executing awards and related modifications of regenerative medicine prototype candidates as subawards to the AFIRM CC,
- Facilitate collaborations with intramural DoD laboratories where appropriate, and
- Provide synchronization and integration of Awardee efforts within the AFIRM consortium and with external stakeholders.

3.2 FY24 AFIRM Clinical Trial Awards

The FY24 AFIRM CTA supports the rapid implementation of clinical trials with the potential to have a significant impact on a disease or condition addressed in one of the FY24 AFIRM CTA Topic Areas (see below). Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs, or biologics), devices, clinical guidance, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first in human, phase 0) through large-scale trials that support U.S. Food and Drug Administration (FDA) regulatory filings.

Funding from this award mechanism must support a clinical trial. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

The USG reserves the right to fund portions of the clinical trial under a base award and subsequent optional research phases. **Continued funding** of the clinical trial base award and approval of research options will be **contingent** upon **meeting** mutually agreed upon **milestones** as determined by the CCCRP Sponsor's Office Technical Representative (SOTR) and USAMRAA.

3.3 FY24 CTA AFIRM Focus Areas

All proposals for FY24 AFIRM CTA funding must specifically address one of the FY24 Focus Areas as directed by the CCCRP and have direct relevance to active-duty Service Members, Veterans, and/or military beneficiaries. The AFIRM implements a portfolio-driven approach within Focus Areas as a framework to address critical gaps in research and product development**.** A portfolio approach helps to ensure that all Focus Areas are being addressed with the most relevant science and technology available.

The FY24 AFIRM Focus Areas are listed in below:

- Focus Area #1: Craniomaxillofacial Regeneration
- Focus Area #2: Extremity Regeneration
- Focus Area #3: Genitourinary/lower abdomen Reconstruction
- Focus Area #4: Skin Regeneration
- Focus Area #5: Ex-vivo/on demand Blood
- Focus Area #6: Cellular therapies for Trauma and Critical Care

Within these Focus Areas, projects impacting far-forward medical care and/or polytrauma are of particular interest. Projects that emphasize traumatic brain injury, stroke applications, hemorrhage control, or sepsis applications are not of interest for this RPP. Please refer to the CCCRP program site, https://cccrp.health.mil/Portfolios/Pages/Regenerative-Medicine.aspx for additional detail.

If the research proposed does not specifically address one of the FY24 AFIRM Focus Areas, then the AFIRM CC and/or the CCCRP reserve the right to administratively withdraw the application. The AFIRM CC and/or the CCCRP reserve the right to reassign the application's Focus Area if submitted to an incorrect Focus Area.

3.4 Clinical Trial Regulatory Requirements

Clinical Trials conducted in the United States or its Territories. If the proposed clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an Investigational New Drug (IND) application to the FDA that meets all requirements under 21 CFR 312 may be required. It is the responsibility of the applicant to provide evidence from the Institutional Review Board (IRB) of record or the FDA if an IND is not required.

If an IND is required, an active IND deemed safe to proceed that covers the proposed trial ***must be in place within 90 days of notification of the AFIRM Clinical Trial Award (this includes clinical trials requesting exception from informed consent under 21 CFR 50.24).*** The IND should be specific for the product (i.e., the product should not represent a derivative or alternate version of the investigational agent described in the IND application) and indication to be tested in the proposed clinical trial. For more information on IND applications, the FDA has provided guidance at https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm. More information about the requirements for obtaining approval for a study involving emergency research can be found within the FDA guidance document "*Exception from Informed Consent Requirements for Emergency Research, Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors"* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ exception- informed-consent- requirements-emergency-research.

If the investigational product is a device, then Investigational Device Exemption (IDE) application to the FDA that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the FDA if an IDE is not required or if the device qualifies for an abbreviated IDE.

If an IDE is required, an active IDE deemed safe to proceed that covers the proposed trial ***must be in place within 90 days of the AFIRM Clinical Trial Award notification (this includes clinical trials requesting exception from informed consent under 21 CFR 50.24).*** The IDE should be specific for the device (i.e., should not represent a derivative or modified version of the device described in the IDE application) and indication to be tested in the proposed clinical trial.

Clinical Trials conducted Overseas. While clinical trials to be conducted overseas can be submitted in response to the RPP, these trials MUST: (1) receive the required approvals from the Host Nation regulatory authorities; (2) be a pilot or Phase 1 safety trial; (3) provide a clinical development plan that includes a pathway to FDA approval; (4) be conducted in Host Nations that are considered Allies of the US Government.

3.5 Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers

All DoD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human Research Oversight (OHRO) prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is ***not*** required; however local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the OHRO web page for additional information (https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo)

3.6 Multi-Institutional Clinical Trials

As of January 20, 2020, U.S. institutions engaged in non- exempt cooperative research ***must*** rely on a single IRB to review and approve the portion of the research conducted at domestic sites (45 CFR 46.114(b)). If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the primary protocol and consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Communication and data transfer between or among the collaborating institutions, as well as how specimens and/or imaging products obtained during the study will be handled, should be included in the appropriate sections of the application. A separate intellectual and material property plan agreed on by all participating institutions will be required in the full proposal submission (invited submissions only).

3.7 Clinical Trials.gov Registration

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health (NIH) clinical trials registry, www.clinicaltrials.gov, prior to initiation of the study.

3.8 Additional Point of Consideration

Industry Partners: Proposed projects are encouraged to include relevant industry partners, especially considering that the eventual goal is to transition products to industry for U.S. FDA approval and/or commercialization.

3.9 Potential Follow-on Tasks

Proposals selected for funding based on responses to this RPP may be funded for one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the Period of Performance. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype.

4 White Paper Preparation

4.1 General Instructions

White Papers should be submitted by the date and time specified on the cover page via the http://afirm.info website application portal. Submitters will need to establish a secure account within the afirm.info website. Instructions are posted at http://afirm.info. Offerors are encouraged to contact the Point-of-Contact (POC) identified herein up until the White Paper submission date/time to clarify requirements (both administrative and technical in nature).

The White Paper format (**Section 8 of this RPP**) provided in this RPP is mandatory. Offerors are required to submit a Study Timeline/ Schedule and Rough Order of Magnitude (ROM) pricing in accordance with the White Paper template (**Section 8.1 and 8.2 of this RPP**).

4.2 Instructions for the Preparation & Submission of the Stage 1 White Paper

Offerors submitting White Papers in response to this RPP shall prepare all documents in accordance with the following instructions.

Offerors should submit files in PDF format: Font – Times New Roman 12; with one-inch margins on no larger than 8.5 x 11-inch paper. Include header listing of PI and brief application title. Include footer listing of organization and date of submission.

Required Submission Documents (6):

- **Tab 1 - White Paper Narrative:** one PDF document, limited to ten (10) pages plus a cover page (11 pages total). 20MB or lower. See Section 8 of this RPP for template.
- **Tab 2 – Study Timeline/Schedule:** PDF document limited to one page. See Section 8.1 of this RPP for template.
- **Tab 3 - Acronyms and Abbreviations:** PDF document. Single spaced, no page limit.

- **Tab 4 - References:** PDF document limited to one page. List the references cited (including URLs if available) in the White Paper using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
- **Tab 5 - Key Personnel Biographical Sketches:** One PDF document (5MB or lower) ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished. NIH format is preferred. **Five-page limit per individual.**
- **Tab 6 - Rough Order of Magnitude (ROM) budget:** PDF document limited to two pages. See Section 8.2 of this RPP for template.

White Papers exceeding the page limits specified above will not be accepted.

Note that FDA approval must be obtained within 90 days of completed award negotiations. The clinical trial should start within 180 days of completed award negotiations. Otherwise, the award may be cancelled, and the funding directed to an alternative proposal.

Neither WFIRM nor CCCRP will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. **If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

A receipt confirmation will be provided by email. Offerors may submit in advance of the deadline**.**

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.3 Stage 2: Full Proposal (for Only Those Offerors Recommended for Stage 2)

Offerors that are recommended for Stage 2 will receive notification letters which will serve as the formal request for a Full Proposal. These letters will contain specific submission requirements. However, it is anticipated that Offerors who are invited to participate in Stage 2 will be required to submit the following information. Templates for the documents will be made available to applicants selected for full proposal submission.

- Technical Proposal
- Cost Proposal Narrative
- Cost Proposal
- Warranties and Representations
- Statement of Work (SOW)/Milestone Payment Schedule (MPS)
- Current and Pending Support
- Intellectual Property and Data Rights Assertions
- Regulatory and Commercialization Strategy and Collaborations

Freedom of Information Act
To request protection from Freedom of Information Act disclosure as allowed by 10 U.S.C. §552, offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis.

Telecommunications and Video Surveillance
Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation.

4.4 Proposal Preparation Costs
The cost of preparing White Papers (and, potentially, a Full Proposal) in response to this RPP is not considered a direct charge to any resulting award or any other contract. Additionally, the Assessment Fee (see Section 2.6 of this RPP) is not considered a direct charge to any resulting award or any other contract.

5 Selection

5.1 Preliminary Screening
The AFIRM CC will conduct a preliminary screening of submitted White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the AFIRM CC. Additionally, the Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

5.2 White Paper (Stage 1) Review
The FY24 AFIRM CTA uses a two-step review process. The AFIRM CC will conduct an initial evaluation of the White Papers (step one) based on an independent review and assessment of the work proposed against stated source selection criteria and evaluation factors. The CCCRP will then conduct a programmatic review (step two), which includes an emphasis on military health impact and relevance and overall AFIRM portfolio considerations.

After completion of the evaluation, Offerors will be notified by the AFIRM CC as to whether they are invited to submit Full Proposals. Offerors will not receive feedback (e.g., a critique of strengths and weaknesses) on their White Paper.

The CCCRP is responsible for final determination of invitations to submit a full proposal. Note that CCCRP may suggest/require changes to the research objectives outlined in the proposal to better align the proposed project to Focus Area needs and/or impact as part of the full proposal invitation.

The evaluation factors are described below and are of equal importance.

Evaluation Factors

1. Technical Approach
2. Military Relevance and Impact
3. Team and Experience
4. Cost Reasonableness

Evaluation Factor 1 – Technical Approach: This factor will evaluate the relevancy, thoroughness, completeness, and impact of the proposed approach (e.g., the technical merit) and how well the proposal defines and meets the technical requirements described within the White Paper Narrative template and the Study Timeline/Schedule.

Evaluation Factor 2 - Military Relevance and Impact: The degree to which the proposed clinical trial, if successful, will have an impact on accelerating the movement of a promising intervention into clinical application. How well the research will address a health care issue relevant to military Service Members, Veterans, and/or beneficiaries.

Evaluation Factor 3 – Team and Experience: This factor will evaluate the project team's expertise, personnel identified as key (those who will contribute significantly to the proposed research project), and experience shall demonstrate an ability to execute the proposed project in an efficient and effective manner (to include addressing USAMRDC's OHARO approval requirements).

5.3 Definition of General Terms Used in Evaluation Factors 1 – 3:

Significant Strength – An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Strength – An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness – A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Weakness – A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency – A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

Factor 4 – Cost Reasonableness: Assessment of the cost of the project to determine: i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be based on the following ratings: Sufficient, Insufficient or Excessive. See the definitions of these ratings below:

SUFFICIENT - The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project

INSUFFICIENT - The estimate is lower than what is considered appropriate to successfully complete the proposed project.

EXCESSIVE - The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

5.4 Full Proposal (Stage 2) Evaluation (Only for Offerors Recommended for Stage 2)

Full Proposal (Stage 2) Evaluation will utilize a two-step review process similar to the White Paper Stage (Stage 1). Details will be provided to those invited for a Full Proposal.

5.5 Award Recommendation

Following review and evaluation of the full proposals by AFIRM CC, the CCCRP will perform proposal source selection. This will be conducted using the process detailed in Section 5.3. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. **Select the proposal (or some portion of the proposal) for award**
2. **Place the proposal in the Basket if funding currently is unavailable; or**
3. **Reject the proposal (will not be placed in the Basket)**

The CCCRP is responsible for final determination of award recommendations.

Note that the white paper and proposal reviews and award process may involve the use of contractor subject matter experts (SMEs) serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, prior to accessing any proposal submission to protect information contained in the Proposal.

6 Points-of-Contact

Questions concerning the application process can be sent to help@afirm.info. Note that questions and answers may be posted on the AFIRM CTA announcement page to assist other applicants. Please allow 24 hours for a response.

7 Acronyms/Abbreviations

ACURO	Animal Care and Use Review Office
AFIRM	Armed Forces Institute of Regenerative Medicine
CC	Coordinating Center
CCCRP	Combat Casualty Care Research Program
CTA	Clinical Trial Award
DoD	Department of Defense
EC	Ethics Committee
F&A	Facilities and Administrative Costs

FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
Government	U.S. Government, specifically the DoD
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
M	Millions
MHS	Military Health System
MHSRS	Military Health System Research Symposium
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
OTA	Other Transaction Agreement
PDF	Portable Document Format
PI	Principal Investigator
POC	Point-of-Contact
PoP	Period of Performance
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOTR	Sponsor's Office Technical Representative
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
WFIRM	Wake Forest Institute for Regenerative Medicine

8 White Paper Template

Cover Page (1 page)

[Title of White Paper]

[CTA Focus Area, check only one]

- ☐ Focus Area #1: Craniomaxillofacial Regeneration
- ☐ Focus Area #2: Extremity Regeneration
- ☐ Focus Area #3: Genitourinary/lower abdomen Reconstruction
- ☐ Focus Area #4: Skin Regeneration
- ☐ Focus Area #5: Ex-vivo/on demand Blood
- ☐ Focus Area #6: Cellular therapies for Trauma and Critical Care

[Principal Investigator]
Address: [Address of PI]
Phone Number: [Phone Number of PI]
Email Address: [Email Address of PI]

[Institution]
Address: [Address of Offeror]
Phone Number: [Phone Number of Offeror]
Email Address: [Email Address of Offeror]
Unique Entity Identifier (UEI) #: [UEI #]
CAGE Code: [CAGE code]

Statement that "This White Paper is submitted pursuant to the "AFIRM 001 RPP."

[Offeror] certifies that, if selected for an Award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[Offeror] certifies that this White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

Date of submission and signature of official authorized to obligate the institution contractually

Signature	
Name	
Title	
Date	

White Paper (10 pages)

Title: [Insert descriptive title of project]

CTA Focus Area: [Identify which CTA Focus Area this proposal is intended for].

Principal Investigator: [Insert name, organization, email address, phone number.]

Alternate Submitter: [If assistance is needed for submission of this proposal, insert name, organization, email address, and phone number of alternate submitter.]

Background: [Briefly state the problem that the White Paper is addressing. List intended Focus Area and how proposed clinical trial addresses a critical need within that Focus Area.]

Test Materials
- Describe the clinical intervention, medical drug, biologic, device, or human exposure model to be tested and the projected outcomes or measures.
- Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
- Concisely describe the production/manufacturing plan for the test materials proposed.

Study Design/Clinical Protocol
- Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology.
- Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples.
- Describe clinical trial site(s) and capabilities for conducting the proposed clinical trial

Personnel and Environment
- List key personnel, roles, and qualifications to participate in the clinical trial.

Statistical Plan and Data Analysis
- Describe the data collection plan, statistical model, and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled or number of human samples to be studied (per site, as applicable).

Relevance to Military Health
- Describe how the project has direct relevance to the health of military Service Members, Veterans, and/or other Military Health System beneficiaries.
- Describe how the intervention would be used in the Military.
- Describe the impact on Military Health if intervention is successful.

Regulatory Strategy

- Describe previous interactions with the FDA or Host Nation regulatory authority related to this proposed prototype solution.
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.

8.1 Study Timeline/Schedule (one page limit)

- Describe the study timeline/schedule, including visits/follow-up.

See the example below.

Schedule of Study Visits Example*				
	Visit 1 (Month #)	Visit 2 (Month #)	Visit 3 (Month #)	Visit 4 (Month #)
Informed Consent	X			
Medical History	X			
Complete Physical Exam	X			
Abbreviated Physical Exam		X	X	X
Height	X	X	X	X
Weight	X	X	X	X
Vital Signs	X	X	X	X
Pharmacokinetics		X		
Randomization	X			
Administration of Study Drug	X	X	X	X
Counting of Returned Study Drug		X	X	X
Concomitant Medication Review	X	X	X	X
Adverse Experiences	X	X	X	X

8.2 Rough Order Magnitude (ROM) Pricing: The Offeror must provide an estimate based on the technical approach proposed in the Enhanced White Paper. The following ROM pricing example format shall be included in the Enhanced White Paper (the number of columns should reflect the proposed PoP, i.e., add or delete the yearly budget columns as needed). NOTE: If invited to Stage 2, the total cost to the Government must not significantly increase from the estimate provided in the ROM (unless otherwise directed by the Government) as award recommendations may be based upon proposed costs within the Enhanced White Paper. Use the example table format and template below to provide the ROM pricing. The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table. If selected for award, a full cost proposal will be requested.

- The applicant may request funding for a project that may have a period of performance less than the maximum **4** years.
- For this award mechanism, direct costs must be requested for:
    - Travel/attendance at a 2-day AFIRM meeting in 2025, and in years three and four of the grant.

	Year 1	***Year 2***	***Year 3***	***TOTAL***
Labor	*$ 100,000.00*	*$ 100,000.00*	*$ 100,000.00*	***$ 300,000.00***
Labor Hours	*1,000.0 hrs*	*1,000.0 hrs*	*1,000.0 hrs*	***3,000.0 hrs***
Subcontractors	*$ 50,000.00*	*$ 50,000.00*	*$ 50,000.00*	***$ 150,000.00***
Subcontractors Hours	*500.0 hrs*	*500.0 hrs*	*500.0 hrs*	***1,500.0 hrs***
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	*$0.00*	*$0.00*	*$0.00*	***$0.00***
Gov't/Military Prtnrs / subKTR Hours*	*0.0 hrs*	*0.0 hrs*	*0.0 hrs*	***0.0 hrs***
Consultants	*$ 10,000.00*	*$ 10,000.00*	*$*	***$ 30,000.00***
Consultants Hours	*100.0 hrs*	*100.0 hrs*	*100.0 hrs*	***300.0 hrs***
Material/Equipment	*$ 75,000.00*	*$*	*$ 75,000.00*	***$ 225,000.00***
Other Direct Costs (ODC)		*$ 1,000.00*	*$ 1,000.00*	***$ 3,000.00***
Travel	*$ 5,000.00*	*$ 5,000.00*	*$ 5,000.00*	***$ 15,000.00***
Indirect costs	*$ 48,200.00*	*$ 48,200.00*	*$ 48,200.00*	***$ 144,600.00***
Total Cost	*$ 289,200.00*	*$ 289,200.00*	*$ 289,200.00*	***$ 867,600.00***
Fee (*Not applicable if cost share is proposed)*	*$ 0.00*	*$ 0.00*	*$ 0.00*	***$ 0.00***
Total Cost (plus Fee)	*$ 289,200.00*	*$ 289,200.00*	*$ 289,200.00*	***$ 867,600.00***
Cost Share (if cost share is proposed then fee is unallowable)	*$ 290,000.00*	*$ 290,000.00*	*$ 290,000.00*	***$ 870,000.00***
Total Project Cost	*$ 579,200.00*	*$ 579,200.00*	*$ 579,200.00*	***$ 1,737,600.00***

EXAMPLE

* Use the row above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (Military Health System (MHS) facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

Estimate Rationale: [The Offeror must provide a brief rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.]

Cost Share [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are **encouraged** to discuss the ability to bring leveraged funding/cost share to complete the project goals.]