USAMRMC STRATEGIC COMMUNICATION PLAN

ARMED FORCES INSTITUTE OF REGENERATIVE MEDICINE (AFIRM)

MISSION

The Armed Forces Institute of Regenerative Medicine is dedicated to repairing battlefield injuries through the use of regenerative medicine technology.

BACKGROUND

Conventional weapons and the destructive force of improvised explosive devices ravage face, neck, head and limbs, causing massive trauma and tissue loss. These injuries can take years to treat and often result in significant lifelong impairment. The field of regenerative medicine holds great potential for treating military personnel with these disfiguring and disabling injuries. Regenerative medicine employs a variety of techniques to prompt the body to regenerate cells and tissues. The ultimate goal is to deliver advanced therapies capable of making our Wounded Warriors whole.

The AFIRM I began in March 2008 when the U.S. Army Medical Research and Materiel Command, in partnership with the Office of the Assistant Secretary of Defense for Health Affairs, the Office of Naval Research, the U.S. Air Force, the National Institutes of Health and the Department of Veteran Affairs established the award to focus research in regenerative medicine on the treatment of battlefield injuries.

The AFIRM I was a multi-institutional, interdisciplinary network of universities, military laboratories and industy partners under the framework of a cooperative agreement. The network is designed to promote seamless integration of development, from basic science research through translational and clinical research, as the best means of bringing regenerative medicine therapies to practice. The

> *"Regenerative medicine employs a variety of techniques, often using the patient's own cells combined with degradable biomaterials and/or growth factors, to prompt the body to regenerate cells and tissues. The ultimate goal is to deliver advanced therapies capable of making our wounded warriors whole."*

AFIRM I exceeded expectations for the first 5 years of funding by supporting 11 clinical trials and treating more than 200 patients with novel treatment strategies in wound repair and tissue replacement.

The success of the AFIRM I led to a new cooperative agreement in 2013, awarded through an open and competitive solicitation. The areas of emphasis for research were adjusted to reflect the changing needs of our Wounded Warriors. The AFIRM II research focus areas encompass skin, extremity, craniofacial, genitourinary and vascularized composite tissue transplantation, such as hand and face transplants. The goal for the AFIRM II is to deliver capabilities that will transform the practice of medicine by finding innovative, regenerative medicine solutions to challenging clinical problems for both warfighters and the public at large.

The AFIRM cooperative agreements (the original AFIRM and AFIRM II) and awards under the Broad Agency Announcement, Small Business Innovative Research and other program announcements, are managed by the Tissue Injury and Regnerative Medicine Project Management Office at the U.S. Army Medical Materiel Development Activity.

QUESTIONS & ANSWERS

Q *What is the Armed Forces Institute of Regenerative Medicine?*

A The Armed Forces Institute of Regenerative Medicine is dedicated to repairing battlefield injuries through the use of regenerative medicine. The AFIRM is managed and funded through the USAMRMC, with additional funding from the OASD(HA), the ONR, the USAF, the NIH, the VA as well as local public and private funding.

Q *Which institutions make up AFIRM?*

A The AFIRM I and II awards created a network of civilian academic institutions working with together with military institutions and industry partners. The AFIRM I was comprised of two consortia led by Rutgers University and Wake Forest University. The AFIRM II consortium is led by Wake Forest University.

KEY THEMES AND MESSAGES

Overarching Theme: Delivering on the promise of regenerative medicine for our Wounded Warriors.

Overall aim: Making our Warfighters whole by restoring form, function and appearance.

The DOD established the AFIRM I in 2008 with the mission of developing new products and therapies to treat severely injured warriors. The AFIRM II was awarded in 2013 to continue regenerative medicine efforts for challenging military problems and to capitalizeon advances from the AFIRM 1.

Each of the two AFIRM awards have assembled a world-class group of engineers, scientists and clinicians to make regenerative medicine a reality for our Wounded Warriors.

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Q *How much funding is allocated to the AFIRM?*

A The AFIRM I received $125 million in U.S. Government funding; the consortia also brought in local public and private matching funds, amounting to more than $80 million. The AFIRM II is a five-year effort, with total U.S. Government funding of $75 million. The period of performance started in 2013 and is expected to complete in 2018.

Q *How were the AFIRM consortia chosen?*

A The cooperative agreements for AFIRM I and AFIRM II were awarded through a competitive solicitation process, in response to a U.S. Army Program Announcement. The two consortia in the AFIRM I were chosen from amongst 28 respondents; the AFIRM II consortium from amongst 12 respondents.

Q *When does the AFIRM program start?*

A Research activity under the AFIRM is under way at the individual participating institutions.

Q *What sort of therapies will be developed within the AFIRM?*

A The AFIRM was designed to speed the delivery of regenerative medicine therapies to treat the most critically injured Service Members. There are five major programs: **Burn Repair, Craniofacial Reconstruction, Extremity Repair, Genitourinary Repair and Vascularized Composite Allotransplantation.**

Q *Will AFIRM researchers use embryonic stem cells?*

A No. All of the research now funded through the AFIRM will use adult-derived stem cells taken from the patient or from another consenting adult. Adult stem cells and progenitor cells are an integral part of normal wound healing and the formation of all new tissues. Many of the strategies being developed by the AFIRM seek to improve wound healing and tissue repair by increasing the number or improving the function of adult stem cells. A patient's own cells or, in some cases, cells from another adult are used in conjunction with special drugs called bioactive factors, or with advanced biomaterials that serve as scaffolds for growth of new tissues.

KEY THEMES AND MESSAGES

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The AFIRM addresses five areas: Burn Repair, Craniofacial Reconstruction, Extremity Repair, Genitourinary Repair, and Vascularized Composite Allotransplantation.

Regenerative medicine is cutting-edge medical technology for treating military personnel with debilitating, disabling, and disfiguring extremity injuries and burns.

The multi-institutional, interdisciplinary network of scientists and researchers are dedicated to accelerating the delivery of regenerative medicine to wounded warriors.

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Q *Can these stem cells regenerate entire arms and legs?*

A No, at least not yet. However, the use of these cells, bioactive factors and biomaterials can help injured Service Members to optimize their own capacity to heal and recover by forming new bone, skin, nerves, tendons, muscles and blood vessels to replace damaged tissues. AFIRM collaborators plan to use these new strategies to dramatically speed and enhance the outcome of tissue repair, leading to a more effective return to productive life after injury.

Q *What are tissue scaffolds?*

A Tissue scaffolds are the medical implants of the future: small, porous, tissue-like implants made of fully degradable, specially designed biomaterials that support cells at the site of injury and assist the body in growing new, functional tissue. When the damaged or lost tissue has been successfully replaced by new tissue, the scaffold will have been completely degraded and recycled by the body. Examples are regeneration of damaged or missing sections of bones, nerves, ligaments, blood vessels and skin.

Q *Are companies participating in the AFIRM?*

A Dozens of commercial entities are working with the AFIRM consortia as partners. The American medical device industry has taken a keen interest in speeding these important new therapies to market; not just for injured Service Members, but for civilian patients as well. Commercial participation is encouraged, and this participation, ultimately, will lead to better health care options for all Americans.

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Q *How can other investigators participate in the AFIRM?*

A The first contact should be with a member of the consortium. However, the USAMRMC has an open Broad Agency Announcement intended to solicit extramural research and development ideas. The BAA is a competitive solicitation procedure issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369). The BAA provides a general description of the USAMRMC's research and development programs, including: research areas of interest; general information; evaluation and selection criteria; and proposal/application preparation instructions.

Research funded through the BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge. Research proposal/applications are sought from national, international, for-profit, non-profit, public and private organizations. The BAA is a continuously open announcement; pre-proposal pre-applications and full proposal/full applications may be submitted at any time throughout the 12-month period. (See Federal Acquisition Regulations 35.016). Program announcements also are published throughout the fiscal year to address specific topics in regenerative medicine.

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