USAMRMC
STRATEGIC COMMUNICATION PLAN

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

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.

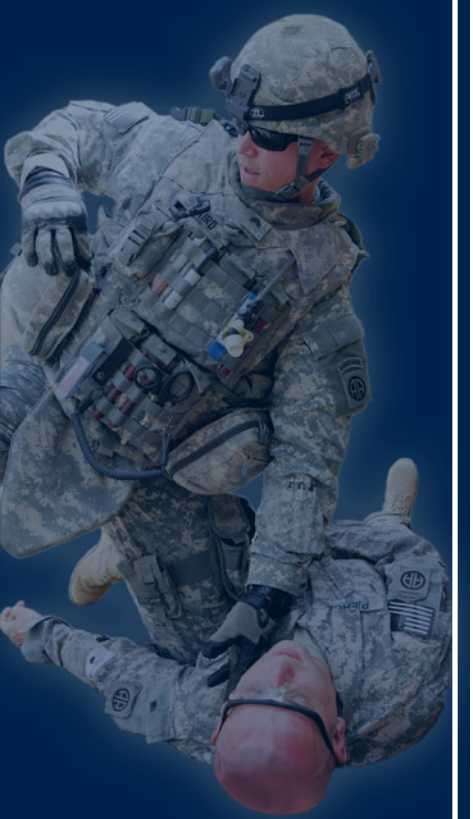
Background

Conventional weapons and the destructive force of improvised explosive devices ravage face, neck, head, and limbs, causing massive trauma and tissue loss. Regenerative medicine has achieved success in the regeneration of human tissues and organs and has great potential for treating military personnel with these disfiguring and disabling injuries. Regenerative medicine uses tissue engineering to prompt the body to regenerate cells and tissues, often using the patient's own cells combined with degradable biomaterials. The ultimate goal is to deliver advanced therapies, whole organs, and engineered fingers and limbs to our wounded Warfighters.

In March 2008, the USAMRMC established AFIRM to conduct research in regenerative medicine for the treatment of battlefield injuries. It was envisioned that integration between basic science research and translational and clinical research is required to bring effective regenerative medicine therapies to practice. AFIRM is a virtual organization consisting of multiple universities working in conjunction with the U.S. Army Institute of Surgical Research (USAISR) under the framework of a 5-year cooperative agreement. The institute is expected to make major advances in wound repair and organ/tissue regeneration. New medical products are expected for patient use in as few as 5 years.

AFIRM is funded by a partnership of the USAMRMC, Office of Naval Research (ONR), the U.S. Air Force (USAF), the National Institutes of Health (NIH), and the Department of Veteran Affairs (VA), along with other participating institutions.

AFIRM's overall goal is to develop enhanced treatment of damaged tissues and organs by using therapies that prompt the body to regenerate lost or damaged tissues from a patient's own cells. This will be achieved by engineering regenerative techniques capable of regrowing muscle, nerves, blood vessels, cartilage, skin, and bone from stem cells taken from the patient (autologous grafting). This technique overcomes problems with rejection caused by grafting cells from other individuals. These tissue constructs will be combined with active prostheses designed to interface with the site of regeneration and also be functional replacements during recovery. The forces and motion from the prosthesis aid and direct the regeneration of the replacement organ or limb. The 5-year goal is to perform clinical trials of autologous muscle, bone, cartilage, nerve, and blood vessel grafts. The longer-term goal is the functional regeneration of limbs.



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Key Themes & Messages

- Overarching Theme: Generating Hope for Wounded Warriors.
- The DoD established AFIRM in 2008 with the mission of developing new products and therapies to treat severely injured warriors.
- AFIRM has assembled a world-class group of engineers, scientists, and clinicians to make regenerative medicine a reality for our wounded warriors.
- AFIRM addresses five areas: Burn Repair, Craniofacial Reconstruction, Limb and Digit Salvage, Scarless Wound Healing, and Compartment Syndrome.
- Regenerative medicine has cutting-edge 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 accelerate the delivery of regenerative medicine to wounded warriors.

Q & A

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

A: AFIRM is a multi-institutional, interdisciplinary network working to develop advanced treatment options for severely wounded service men and women. AFIRM is managed and funded through USAMRMC, with additional funding from the ONR, USAF, the NIH, the VA, and local public and private matching funding.

Q: Which institutions make up AFIRM?

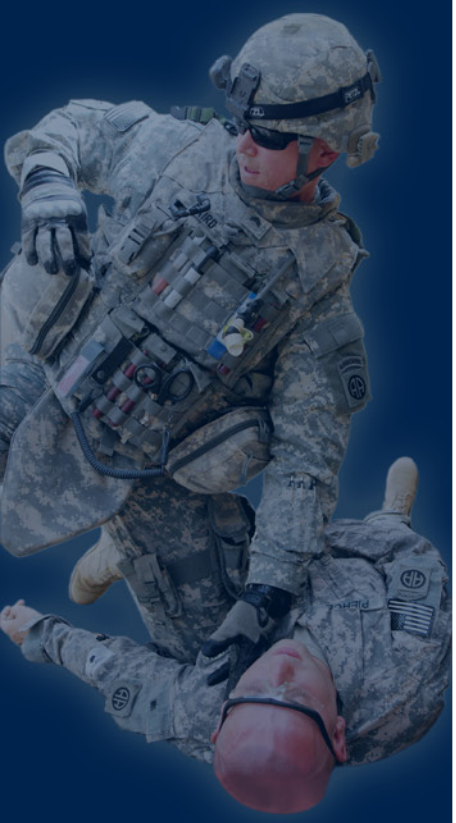
A: AFIRM is made up of two civilian research consortia working with USAISR in Fort Sam Houston, Texas. One consortium is led by Rutgers University and the Cleveland Clinic and one is led by Wake Forest University and The McGowan Institute for Regenerative Medicine at the University of Pittsburgh. Each of these civilian consortia is itself a multi-institutional network.

Q: How much funding is allocated to AFIRM?

A: Each of the civilian consortia was awarded $42.5 million over a 5-year period. In addition, the two consortia are bringing local public and private matching funds amounting to more than $80 million that will be added to their research budgets. In each case, the full amount of the grant was allocated to the lead institution. Those lead institutions are responsible for distributing the funds among their consortium partners according to peer-reviewed work plans that address AFIRM therapeutic objectives.

Q: How were the AFIRM consortia chosen?

A: The process for awarding AFIRM grants began in January 2007, with a Request for Information from USAMRMC. Twenty-eight institutions responded. In April 2007, a draft Request for Proposal was sent to those 28 respondents for comment. In August 2007, a Program Announcement was released by the Army. Seven consortia responded. From those, two finalists were chosen for oral presentations to the Scientific Review Panel in December 2007. Ultimately, both finalists were deemed to have built excellent programs and both were recommended for funding.



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Q: When does the AFIRM program start?

A: Much of the research activity to be funded by AFIRM is already under way at the individual participating institutions. USAMRMC has issued cooperative agreements with the lead institution for each consortium, and work is ongoing.

Q: What sort of therapies will be developed within AFIRM?

A: AFIRM was designed to speed the delivery of regenerative medicine therapies to treat the most critically injured service members from around the world but, in particular, those coming from theaters of operation in Iraq and Afghanistan. There are five major programs: Burn Repair, Craniofacial Reconstruction, Limb and Digit Salvage, Scarless Wound Healing, and Compartment Syndrome.

Q: Will AFIRM researchers be using embryonic stem cells?

A: No. All of the research now funded through 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 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.

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

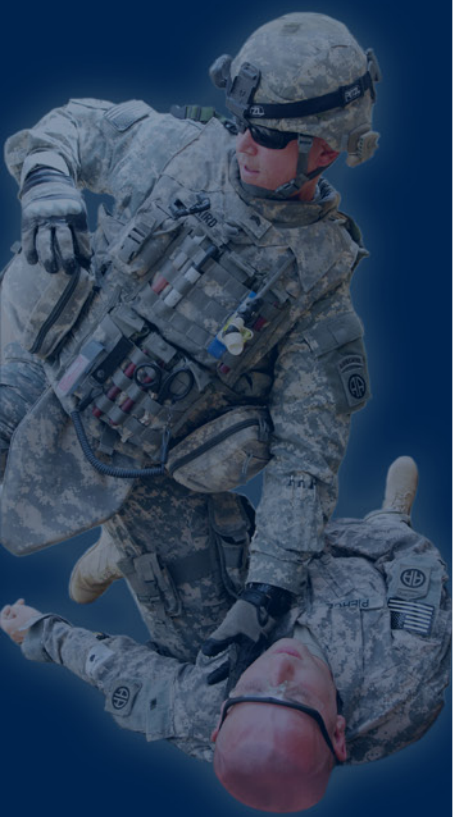
A: No, at least not yet. However, the use of these cells, bioactive factors and biomaterials can help injured service members to optimize their own capacity to heal and recover by forming new bone, skin, nerves, tendons, muscles, and blood vessels to replace damaged tissues. AFIRM collaborators plan 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 AFIRM?

A: Dozens of commercial interests have expressed a willingness to work with the AFIRM consortia as commercialization 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. This participation ultimately will lead to better health care options for all Americans.



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