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World-Leading Surgeons, Scientists, and the Organ Preservation Alliance Applaud Defense Department Initiated First-Ever Government Grant Programs Targeting Organ Banking for Transplants

January 15, 2015, NASA Research Park, Moffett Field, CA – The Organ Preservation Alliance, a Silicon Valley nonprofit working to save millions of lives by catalyzing breakthroughs in the storage of organs, together with world-leading transplant surgeons and scientists on the Alliance's medical and scientific advisory boards, jointly congratulate the U.S. Department of Defense (DoD) on its announcement of the first-ever multi-million dollar grant funding pools dedicated to research on organ and tissue banking technologies.

The DoD will today, via its Tissue Injury and Regenerative Medicine (TIRM) program office open three separate, but complementary, organ cryopreservation grant programs. These programs could together fund research for 20 or more leading American research teams, with strong, individual teams potentially receiving $3-3.5 million across different phase 1 and 2 awards. These business innovation (SBIR) grants are aimed to support U.S. commercialization of science while achieving military as well as civilian health goals.

Sebastian Giwa, PhD, President and CEO of the Organ Preservation Alliance and also speaking for New Organ, said: "This bold step by the DoD will enable the crucial breakthroughs needed to create a future in which we can stop biological time for human organs, in much the way that we have, for decades, been able to bank stem cells, human eggs, sperm, and embryos."

"35% of all deaths in the U.S. could be prevented or substantially delayed by organ transplantation, and this move by the DoD could be a true game changer."

Need for Organs is Vast, DoD Funding Could Transform Transplantation and Save Millions of Lives

"The supply of tissues is one of the major constraints we face in transplantation medicine today, and organ banking technology would dramatically help resolve it. This is a major step forward in the field of transplantation," said Harvard Medical School Professor Bohdan Pomahac.

"Currently, transplant organs cannot be stored for long at all, so a high percentage of viable transplant organs are discarded before matches can be found and helicopter and jet transportation can be arranged. Hearts, for instance, can currently only survive for 4-5 hours outside of a body," said world-leading heart transplant

surgeon, Professor Jacob Lavee. “If we could get longer preservation, so that just half of the wasted hearts and lungs could be used, the U.S. wait-list for these organs would be extinguished in a few years.”

Dr. Gerald Brandacher, Scientific Director of the Composite Tissue Allotransplantation Program at Johns Hopkins heralded this commitment: “People seem to underestimate what could be coming. This is a big step towards a future in which we routinely replace damaged organs and tissues to restore both form and function, in a way that only transplantation allows – replacing ‘like with like’.”

“The ability to build real organ and tissue banks could transform the entire field of transplantation. This commitment from the DoD is taking us one step closer to that reality.”

The DoD’s Three Separate, but Complementary, Grant Programs are Designed to Catalyze Audacious Breakthroughs

The three new DoD grant programs target different, but related, problems in the field. The first program aims to develop fundamental breakthroughs in the low-temperature physics underlying the preservation of living tissues; the second programs focuses on low toxicity cryoprotectants that prevent ice formation in cooled organs; and the third program targets effective and fast rewarming protocols to ‘out-warm’ the ice crystallization process and for restoring function to cooled organs.

“At first look, the challenge of reversible banking of human organs seems daunting, but it can be broken down into a set of tractable sub-problems, each with many potential solutions. The different topics that the DoD is asking scientists to work on, to a large extent cover the set of different sub-challenges that need to be overcome," said leading cryobiologist, Professor Boris Rubinsky at UC Berkeley.

The head of the DoD group that runs these programs, Kristy Pottol, project manager for the Tissue Injury and Regenerative Medicine Project Management Office at the U.S. Army Medical Materiel Development Activity said: “In the context of the important investments the DoD is making in tissue engineering via the Armed Forces Institute of Regenerative Medicine (AFIRM), and the investments in the world’s largest hand and face transplant program, this investment in tissue banking should not only add value on its own by improving current transplantation practices, but could also help support, complement and accelerate tissue engineering breakthroughs.”

Military as well as Civilian Needs Outside of Vital Organs are Immense

“The DoD’s decision to support tissue cryopreservation research is critical to restoring the health and function of our brave service members,” said world-leading cryobiology scientist Mehmet Toner, Professor at Harvard, Mass General and MIT.

"Progress in cryobanking would be game-changing and would enable our ever-improving transplantation abilities to help maimed American servicemen, as well as firefighters, factory workers, or civilians and children around the world injured by landmines,” said Dr. W.P. Andrew Lee, who performed the nation’s first military double-arm transplants and is Director of the Department of Plastic & Reconstructive Surgery at Johns Hopkins.

Dr. Lee’s colleague, Dr. Pomahac at Harvard said: “In addition to scarce availability of vital organs like heart and kidneys, there is a tremendous lack of vascularized composite tissues for transplantation, trauma, reconstructive and regenerative medicine needs. Over 1,600 service members have suffered amputations from injuries in Iraq and Afghanistan and over 4,000 Service members have sustained severe craniomaxillofacial injuries. Being able

to bank complex vascularized tissue would revolutionize the way we can restore these brave young women and men who serve our country."

At the same time that the number of catastrophic combat injuries to limbs and face is unacceptably high, civilian need for solutions to amputations is even greater: "Two million people are living with limb loss in the U.S., with 185,000 amputations conducted each year. Approximately 100,000 of those amputations stem from vascular disease and/or diabetes, and roughly 83,000 are due to trauma, often in young individuals," Dr. Lee added.

Decades of Cryobiology Research, as well as Valuable Understanding and Tools in Other - Often Radically Accelerating - Domains Have Set the Stage for the Needed Breakthroughs

"It is wonderful that the DoD has decided to target complex system cryopreservation at this moment in time. Cryobiologists have been able to preserve individual cells and a wide variety of organized tissues for decades, and even intestinal segments, whole uteri, and to some extent whole ovaries, by freezing. And exciting progress, including my group's ability to cryopreserve and successfully transplant a rabbit kidney, with subsequent life support, by avoiding ice formation entirely, suggests that much more extensive successes may be possible in the future," said Dr. Greg Fahy, Chief Science Officer at 21st Century Medicine.

"With all the possibilities cryopreservation research has opened up, there is now a lot of room for scientists in other fields to come in and apply their knowledge. As a result, we may be on the path to better cryoprotectants, better rewarming techniques, better tools in almost every respect," said Dr. Erik Woods, President of the International Society of Cryobiology.

"Within its set of complementary cryopreservation grant topics, the Department of Defense has wisely identified re-warming of tissue as a key scientific opportunity. Safely re-warming tissue is actually one of the largest barriers to cryopreservation. Ironically, dangerous ice formation happens more quickly when the tissue is warmed than when it is cooled," said Dr. John Bischof, Director of Bioheat and Mass Transfer Lab and Professor at the University of Minnesota, and added: "A number of leading edge technologies can now be brought to bear on the re-warming challenge. Using recent advances in nanotechnology combined with low-frequency radiowave transmission, we can deliver enormous amounts of heat rapidly, evenly, and safely."

Important Move by the DoD in to Ensure that the U.S. does Not Fall Behind China; Large Commercial Value

"China has been making progress lately in the field. The other day, I read a study about an experiment in which Chinese scientists cryopreserved rat legs and successfully transplanted them into recipient rants. It is a shame that China beat us to these important proof-of-concept results, when the U.S. has arguably the best scientists in the world when it comes to cryopreservation. The decision by the DoD to help support these scientists is a great step in the right direction," said Harvard Medical School Professor Bohdan Pomahac.

"Even in the applications where cryopreservation is already clinically available — the banking of cells and simple tissues — progress in organ preservation will lead to better techniques. The market value of these areas is large, and progress in them will in turn lead to further cryopreservation investment. Because of this, targeting organ preservation pushes the overall field of regenerative medicine forward," said President and Chief Science Officer of Cell & Tissue Systems, Dr. Kelvin Brockbank.

Protecting Ovaries of Women with Cancer; Accelerating Drug Development With Less Animal Experiments

"One huge potential application for this technology will be in helping patients who have treatable cancer, but require strong doses of chemo or radiation therapy. In these cases, cryobanking could enable doctors to protect crucially important, but fragile, tissues by removing them, banking them and then transplanting them back into the patient after the gonadotoxic therapy is completed," says world leader in ovary cryopreservation and Professor Pasquale Patrizio, Director of the Yale University Fertility Center.

“Preserving human tissues for research on a broad range of diseases will facilitate and accelerate scientific advances and create impact at the clinic. It can also potentially reduce costs and decrease the need for animals in research. In a similar way, it will also aid drug screening and development reducing cost and time towards new therapies,” Professor Utkan Demirci, Director of Stanford University’s Bio-Acoustic MEMS in Medicine Labs.

"The power of cryopreservation stems from the universality of breakthroughs in one complex tissue system to others. What we learn in preserving liver tissue will help us preserve limb and the knowledge gained from the limb will lead to the preservation of heart, which will ultimately lead to bio-banking of complex tissues and organs for a myriad of clinical applications relevant to the injured servicemen," says Mehmet Toner, cryobiologist and Professor at Harvard, Mass General and MIT.

Stopping Biological Time by Turning Tissue Into a Glassy, Non-Frozen, State

“The process of vitrification, turning the entire tissue directly into a glassy state avoiding freezing and ice damage, has opened up a lot of new possibilities. It's brought us closer to addressing some of the major barriers to large tissue cryopreservation," said Dr. Mike Taylor, world-leader in vitreous cryopreservation approaches of tissue systems and Adjunct Professor at Carnegie Mellon.

Dr. Greg Fahy, Chief Science Officer at 21st Century Medicine, said: “While the ability to store living systems for a few years is probably all we need for organ banks to transform transplantation medicine, vitrification should actually enable storage of biological material for literally as long as anyone would ever want. Cryopreservation virtually stops biological time, indefinitely.”

ABOUT THE ORGAN PRESERVATION ALLIANCE AND NEW ORGAN

The Organ Preservation Alliance is a non-profit incubated at SU Labs at NASA Research Park in Silicon Valley, which is working to catalyze breakthroughs on the remaining obstacles towards the long-term storage of organs by building on recent advances in cryobiology and relevant fields.

These breakthroughs will save and enrich the lives of millions; they will also accelerate progress towards break-throughs in organ tissue engineering. Innovation in these technologies will enable cryobanked, tissue-engineered organs to be available off-the-shelf and on-demand, eventually revolutionizing human health.

The Organ Preservation Alliance is a Founding Partner of New Organ, a collective impact initiative working to address organ disease and injury by coordinating a shared roadmap, prize portfolio, and alliance to catalyze breakthroughs in organ banking, bioengineering, and regeneration.