RECONSTRUCTIVE TRANSPLANT RESEACH PROGRAM

CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

MISSION: Advance science and standardized clinical practice of vascularized composite allotransplantation to improve access, safety and quality of life for catastrophically injured Service Members, Veterans and the American public

Congressional Appropriations FY12-FY24:
$153M total

"I'm glad this funding exists to let me be in the position I'm in now to get some of my independence back and have a hand for holding my daughter's."

Joe Kinan, Hand Transplant Recipient, FY21-FY24 Programmatic Panel Member

SCOPE OF THE PROBLEM

Vascularized composite allotransplantation refers to the transplantation of multiple tissues as a functional unit from a deceased donor to a recipient with a severe injury. Examples of VCA may include hand and face transplants.

Upper extremity limb loss affects **~41,000** Americans[1]

>35,000 head and neck reconstructive procedures occurred in the U.S. in 2020[2]

Only **56** VCAs recorded in U.S. history[3]

RELEVANCE TO MILITARY HEALTH

1,558 military personnel lost a limb in the Iraq and Afghanistan wars[4]

Support for VCA donation of hands and face is higher in Veterans than the general public[5]

PROGRAM PRIORITIES

- Reduce the risks of **immunosuppression**
- Optimize **tissue preservation** strategies
- Develop reliable non-invasive graft **monitoring**
- Understand **psychosocial** factors
- **Standardize** VCA protocols

1 Dillingham TR and Braza DW. Upper Limb Amputations. Essentials of Physical Medicine and Rehabilitation. Second Edition. 2007
2 https://www.donoralliance.org/professional-partners/transplant-centers/
3 https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#
4 https://acl.gov/sites/default/files/programs/2021-04/llam-infographic-2021.pdf
5 Ward S, et al. Transplantation, 105, no.5, 2021: 1116–1124.

PROGRAM IMPACT AND OUTCOMES

Fostering Collaboration Through CONSORT

The RTRP funded the Clinical Organization Network for Standardization of Reconstructive Transplantation

CONSORT Goals: *Galvanize the community around standardizing clinical protocols and clinical practice guidelines for face and hand transplantation and then allow those protocols to be assessed in multi-institutional clinical trials*

Led by Yale University in collaboration with:

- National Academies of Science, Engineering, and Medicine
- Wake Forest University
- Metis Foundation
- Navitas

CONSORT
CLINICAL ORGANIZATION NETWORK FOR STANDARDIZATION OF RECONSTRUCTIVE TRANSPLANTATION

www.consortrial.org

PHASE 1
2 YEARS, $3M

- **STEP 1** — Establish Clinical Network
- **STEP 2** — Develop Standardized Protocols and Clinical Practice Guidelines
- **STEP 3** — Develop Clinical Trial Applications
- **STEP 4** — Regulatory Approvals

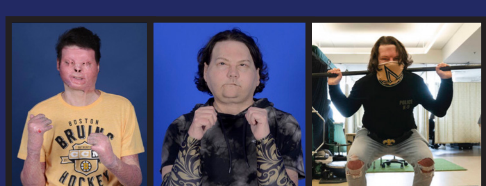
PHASE 2
4 YEARS, $10M

- **STEP 1** — Conduct Clinical Trials to Assess Standardized Protocols and CPGs

TESTIMONIALS – IMPROVING QUALITY OF LIFE AND PATIENT OUTCOMES

"Words cannot describe how I feel. I am overwhelmed with gratitude and feel very blessed to receive such an amazing gift." [6]

Robert Chelsea, *Brigham and Women's Hospital,* first Black American face transplant recipient



"I feel like it's a big step in science. I'm pretty proud to be a part of it." [7]

Joe DiMeo, *NYU Langone Health,* first successful combination face and double hand transplant

RESEARCH BREAKTHROUGHS — MAKING A DIFFERENCE

Created the first quantitative assessment of daily hand use demonstrated **greater** and **more natural use** of upper limbs in hand transplant recipients compared to prosthesis users

Demonstrated **first evidence** that Grade 1 or mild rejection in human face transplant recipients is **not** a **pathological state**, changing clinical care guidelines

Identified **Matrix Metalloproteinase 3** as a **sensitive blood biomarker** for identifying degree of graft rejection

Developed **patient-centered informational resources** regarding ethical and psychosocial factors for informed consent processes

---

6 http://www.brighamandwomens.org/about-bwh/newsroom/press-releases-detail?id=3464

7 https://nypost.com/2021/02/03/face-and-hand-transplant-recipient-steps-out-for-the-first-time

Point of Contact: CDMRP Public Affairs
dha.detrick.cdmrp.mbx.public-affairs@health.mil