

# **Request for Information (RFI): Quality of Life and Psychosocial Aspects of Vascularized Composite Allotransplantation**

## **Key Dates**

Release Date: May 16, 2019

Response Deadline: June 13, 2019

## **Issued by**

Reconstructive Transplant Research Program (RTRP)

## **Purpose**

This RFI is for information and planning purposes only, and should not be construed as a solicitation or an obligation on the part of the RTRP or the Department of Defense (DoD). The RTRP is soliciting input regarding the quality of life (QoL) and psychosocial aspects of vascularized composite allotransplantation (VCA) to better understand the most critical questions that need to be addressed. The RTRP seeks responses from scientists and clinicians in the reconstructive transplant and related fields as well as VCA recipients, significant others/family members, candidates, and caregivers; amputees and others considering VCA; organ procurement organizations; and third party payers. Information received will be considered in the development of future funding opportunities.

## **Background**

Research regarding QoL and psychosocial factors in the reconstructive transplant field is in its infancy, but its importance is well recognized by patients, caregivers, clinicians, scientists, and others. The RTRP has solicited proposals in the QoL and psychosocial realm of VCA since fiscal year 2015 (FY15) and has invested \$6.9 million (M) toward this effort through FY17, for a total of 7 projects across 15 organizations. Another two projects totaling \$3.0M have been recommended for funding in FY18 in the QoL/psychosocial research space. Topics addressed in these RTRP-funded projects include:

- **Factors influencing treatment decisions**
  1. Identify motivations, values, preferences, and expectations of VCA candidates and their caregivers when making a treatment choice (i.e., VCA vs. other options) and the development of a discussion aid to assist in treatment decision-making.
  2. Develop a shared decision-making process to help military Veterans and their caregivers make authentic treatment decisions and optimize the results of VCA.
  3. Identify information needs and expectations regarding upper extremity (UE) VCA, develop educational materials about UE VCA, and optimize the informed consent process for UE VCA candidates.
  
- **Criteria for impacting successful patient selection**
  4. Identify association between psychosocial factors and post-operative outcomes in UE VCA (e.g., medication non-adherence, rejection episodes, graft loss).
  5. Develop an algorithmic, data-based protocol of psychosocial factors for optimal patient selection in UE VCA.

- **Factors influencing donor registration and authorization**
  6. Assess awareness and perceptions of VCA donation, and identify psychosocial factors that limit donor offers/donor authorization for VCA .
  7. Develop a communication approach and training module for organ procurement organization (OPO) staff to discuss VCA donation with donor families.
  8. Develop educational materials to increase public knowledge, understanding, perceptions of comfort, and willingness to donate VCA organs.
  
- **Development of QoL measures**
  9. Identify the QoL and psychosocial domains most important to individuals involved in the UE VCA process, and validate standardized outcome measures most important to UE VCA patients.

There are a number of challenges that impede VCA-related QoL and psychosocial research. One of these challenges is the relatively small number of VCA procedures that have been performed worldwide (i.e., over 35 face transplants<sup>1</sup> and over 140 hand/arm transplants<sup>2</sup>). Therefore, the number of potential patients to be recruited into a QoL or psychosocial study is limited, and those patients willing to participate might only agree to a limited number of studies. To ensure we do not overburden the limited number of patients, it is critically important that the studies performed are asking the right questions, are well designed, and are appropriately powered.

Another challenge is the heterogeneity in the VCA recipient population, which could confound responses in QoL and psychosocial studies. For example, QoL may vary in hand/arm transplant recipients depending on whether the transplant was unilateral or bilateral, or above or below the elbow. The type of VCA transplant received is also a distinguishing factor, as different QoL domains may exist for UE and craniofacial transplant recipients. Yet another challenge is locality and cultural identity, as QoL/psychosocial responses may vary regionally, by VCA Center more specifically, or by cultural community (e.g., ethnic, religious, etc.). For all of these reasons, collaboration across multiple VCA centers may be most ideal for capturing the elements of variability.

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<sup>1</sup> Giatsidis G, Sinha I, and Pomahac B. Reflections on a Decade of Face Transplantation. *Ann Surg.* 2017. 265(4):841-846.

<sup>2</sup> Shores JT, Malek V, Lee WPA, and Brandacher G. Outcomes after hand and upper extremity transplantation. *J Mater Sci Mater Med.* 2017. 28(5):72.

**Information Requested**

Given the limited amount of RTRP funding, and funding for VCA in general, these funds must be spent wisely and carefully. Toward this end, the RTRP seeks the following information from the VCA community:

Select of of the identifiers from the drop down box that describes your relationship the VCA field:

If you selected “other” please describe:

1. From your perspective, identify the top three QoL/psychosocial topics/questions that need to be addressed in the reconstructive transplant/VCA field.

Topic/Question 1:
Topic/Question 2:
Topic/Question 3:

Please indicate whether you feel that any of your three topics/questions are already being addressed by the RTRP-funded projects listed in the background section above (if so, then match the Topic/Question to the related RTRP-funded project number), and specify whether additional value may be gained through soliciting additional proposals on the topic/question.

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If your topic three topics/questions are all being addressed by currently funded projects, please list a fourth topic of high importance that has not been addressed.

Topic/Question 4 (optional):

2. What barriers exist that prevent research collaboration among VCA centers? What could be done to facilitate better collaboration?

3. Is there knowledge to be gained from QOL/psychosocial studies in other related fields (e.g., solid organ transplantation, prosthetics, etc.) that can inform the VCA field? Would it be valuable to identify domains of overlap and uniqueness? Is there more that the RTRP can be doing to facilitate the translation of research from other fields to VCA?

4. What QoL/psychosocial questions need to be answered to assist in the effort toward VCA coverage by third party payers?

5. For each of the topics below, rate the importance of each to the VCA field. For each topic, please score each on a scale of 1 to 5 (with 1 being the highest priority, 2 being high priority, 3 being medium priority, 4 being low priority, and 5 being not valuable). **Each topic should be considered independently, so it is acceptable to use the same number more than once.**

Considering that VCA is a life-enhancing treatment rather than a life-saving one, what QoL domains are most important for VCA recipients?

1                      2                      3                      4                      5                      No Opinion

Develop a QoL model based on the science of QoL in the psychosocial arena, and identify those domains in which VCA-related considerations overlap with general QoL considerations as well as those that are specific to VCA.

1                      2                      3                      4                      5                      No Opinion

Develop outcome measures that are sensitive to change and individual variation.

1                      2                      3                      4                      5                      No Opinion

Does the relationship between the patient and the clinician affect outcomes?

1                      2                      3                      4                      5                      No Opinion

How do psychosocial needs change for VCA recipients over time, and would routine counseling improve outcomes?

1                      2                      3                      4                      5                      No Opinion

6. Please provide any additional comments in the field below.

**How to Submit a Response**

All responses to the RFI must be submitted via email to the RTRP mailbox ([usarmy.detrick.medcom-cdmrp.mbx.cdmrp-rtrp@mail.mil](mailto:usarmy.detrick.medcom-cdmrp.mbx.cdmrp-rtrp@mail.mil)) by June 13, 2019. Please use the subject line, “RFI – QoL and psychosocial components of VCA.”

Responses to this RFI are voluntary. The responses will be reviewed by RTRP staff and the FY19 RTRP Programmatic Panel. Individual feedback will not be provided to any respondent. The RTRP and the DoD reserve the right to use any submitted information on the CDMRP website, in reports, in summaries of the state of the science as well as in the development of future funding opportunities.

The RFI is for information and planning purposes only, and shall not be construed as a solicitation, grant, or cooperative agreement, or as an obligation on the part of the RTRP or DoD to provide support for any ideas identified in response to it. The DoD will not pay for the preparation of any information submitted or for the DoD’s use of such information. No basis for claims against the DoD shall arise as a result of a response to this RFI or from the DoD’s use of such information.