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**TITLE:** Developing a Tool for Predicting Nonadherence in VCA Recipients

**PRINCIPAL INVESTIGATOR:** Dorry Segev, MD PhD

**CONTRACTING ORGANIZATION:** Johns Hopkins University

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**TYPE OF REPORT:** Final

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#### 14. ABSTRACT

Psychosocial factors are important predictors of medication adherence, and subsequently graft survival, in solid organ transplantation (SOT). Early experiences suggest this may be the case in Vascular Composite Allotransplantation (VCA) as well. We assessed psychosocial factors and medication adherence in VCA recipients.

Using validated tools, we surveyed upper-extremity transplant recipients at two centers to assess depression (Patient Health Questionnaire-9), personality (Ten-Item Personality Inventory), anxiety (Generalized Anxiety Disorder 7-item Scale), PTSD (Primary Care PTSD Screen for DSM5), and social support (Multidimensional Scale of Perceived Social Support). Medication adherence among VCA recipients at two centers was assessed by a member of the clinical research team using the recipient's medical record.

Medication adherence was reported for 14 VCA recipients and 9 recipients completed psychosocial assessments. Median (IQR) years since transplant was 8.5 (5-11). Most recipients were believed to be adherent to their immunosuppression, however 3 (21%) recipients were believed to be non-adherent and a member of the clinical team had discussed non-adherence at least once with 5 (36%) recipients. Two recipients (14%) experienced loss of their transplanted extremity, however the clinical team did not believe they were non-adherent. Median (IQR) number of rejection episodes was 5 (2-10). Most participants (71%) were on a multi-drug immunosuppression regimen.

Results from the psychosocial assessment indicated that one participant (11%) screened positive for PTSD and all had high levels of social support. Four participants (44%) demonstrated mild anxiety and 3 participants (33%) demonstrated minimal or minor symptoms of depression. A High level of conscientiousness was demonstrated by 8 participants (89%), high levels of emotional stability and openness to experiences were each demonstrated by 6 participants (67%) and high levels of extraversion and agreeableness were each demonstrated by 5 participants (56%).

While most participants in this study were believed to be adherent to their immunosuppression, the clinical team had concerns that three were non-adherent. Participants in the psychosocial assessment appeared to have good social support and high levels of conscientiousness, which have been associated with better adherence to immunosuppression in SOT. However they may be at risk for depression and anxiety, which has been associated with medication non-adherence in SOT.

**15. SUBJECT TERMS**

Vascular Composite Allotransplantation  
Vascular composite Allograft  
VCA  
Reconstructive transplantation  
Psychosocial  
Medication non-adherence  
Medication adherence  
Compliance  
Social support  
Psychological factors

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Vascular composite allotransplantation (VCA) is being performed with increasing functional and sensory success, however little is known about the psychosocial implications of VCA and how these contribute to post-transplant outcomes. We hypothesize that psychological factors and social support are important independent predictors of post-VCA outcomes, including medication adherence, rejection, and graft loss. In this retrospective cohort study, we will characterize personality attributes, depression, anxiety and social support among VCA recipients. We will then quantify the association between psychological factors/ social support and post-transplant outcomes.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Vascular Composite Allotransplantation, Vascular composite Allograft, VCA, Reconstructive transplantation, Psychosocial, Medication non-adherence, Medication adherence, Compliance, Social support, Psychological factors

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

**What were the major goals of the project?**

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

**Specific Aim 1: To characterize personality attributes, depression, anxiety, and social support among VCA recipients using several validated measures. (100% complete)**

Major Task 1: Collect demographic, clinical, comorbidities, and socioeconomic data from participants (100% complete)

Subtask 1: Medical record abstraction (100% complete)

Subtask 2: Baseline participant questionnaire (100% complete)

Major Task 2: Collect data on psychosocial factors from participants (100% complete)

Subtask 1: Personality assessment (100% complete)

Subtask 2: Depression and anxiety screening (100% complete)

Subtask 3: Social support assessment (100% complete)

Major Task 3: To characterize psychosocial factors among participants (100% complete)

Subtask 1: Exploratory data analysis (100% complete)

*Milestones: Identification and characterization of all pertinent psychosocial factors and potential confounders within study population (100% complete)*

**Specific Aim 2: To quantify the association between psychological factors/social support and the post-operative medication non-adherence, rejection, and graft loss.**

Major Task 1: To quantify independent association between psychosocial factors and non-adherence (100% complete)

Subtask 1: Multivariate logistic regression modeling (100% complete)

Major Task 2: To quantify independent association between psychosocial factors and rejection (100% complete)

Subtask 1: Multivariate logistic regression modeling (100% complete)

Major Task 3: To quantify independent association between psychosocial factors and graft loss (100% complete)

Subtask 1: Multivariate cox proportional hazard modeling (100% complete)

*Milestones: Identification of important psychosocial risk predictors for outcomes following VCA*

**Specific Aim 3: To create a risk prediction calculator which determines the likelihood of medication non-adherence for VCA recipients prior to undergoing transplantation.**

Major Task 1: Create risk prediction tool for post-VCA medication non-adherence

Subtask 1: Create model using coefficients from regression modeling performed in Aim 2

Subtask 2: Evaluate predictive accuracy

Major Task 2: Make tool available to providers and patients via website

Subtask 1: Create website

**What was accomplished under these goals?**

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

1) Major activities

- a. The study team researched updates in the fields of VCA and psychosocial evaluation. Potential study instruments to measure psychosocial factors were gathered and distributed to faculty for review and assessment. Based on this research and feedback, we identified an effective and efficient collection instruments to achieve the study aims.
- b. Completed regulatory human subjects research requirements at Johns Hopkins (JH) and subsequent expansion to Christine M Kleinert Institute (CMKI)
- c. We administered the psychosocial questionnaire to VCA recipients at JH and CMKI (n=9, 75% response rate among eligible VCA recipients at JH and CMKI).
- d. We abstracted adherence information and transplant outcomes from medical records of study participants (n=14)
- e. We conducted exploratory data analysis to characterize psychosocial factors and medication adherence among study participants

## 2) Specific Objectives

- a. Study instrument finalization
- b. Medical record abstraction
- c. Baseline participant questionnaire
  - i. Personality assessment
  - ii. Depression and anxiety screening
  - iii. Social support assessment
- d. Exploratory data analysis
- e. Assessment of feasibility of statistical modeling and risk prediction

## 3) Methods

- a. Using validated tools, we surveyed 9 upper-extremity transplant recipients at two centers to assess depression (Patient Health Questionnaire-9), personality (Ten-Item Personality Inventory), anxiety (Generalized Anxiety Disorder 7-item Scale), PTSD (Primary Care PTSD Screen for DSM5), and social support (Multidimensional Scale of Perceived Social Support).
- b. Medication adherence among VCA recipients at two centers was assessed by a member of the clinical research team using the recipient's medical record. Medication adherence was reported for 14 VCA recipients.

## 4) Significant results or key outcomes

- a. Medication adherence and demographic information was reported for 14 participants, and psychosocial assessments were completed by 9 participants. All VCA recipients were Caucasian (n=14), and most were male (n=13, 93%, Table 1).
- b. Median (IQR) years since transplant was 8.5 (5-11), and most received upper extremity transplants (n=13, 93%). Median (IQR) number of rejection episodes was 5 (2-10), but few participants had lost their VCA graft (n=2, 14.3%, Table 1).
- c. Most recipients were covered by private insurance (n=10, 71%) and most were on a multi-drug immunosuppressive regimen (n=10, 71%, Table 1).
- d. Most recipients were believed to be adherent to their immunosuppressive medication (n=11, 79%), but three were believed to be non-adherent (21%).
- e. Providers reported frequent rashes and resistance to having labs drawn in one participant and episodes of confusion leading to non-adherence in a second patient. Non-adherence was suspected in the third patient based on communication from their spouse.
- f. All participants suspected of being non-adherent were on multi-drug regimens, but no statistically significant difference in adherence was detected when comparing multi- and single-drug regimens (p=0.5).
- g. Providers had discussed non-adherence with five recipients, and providers rated all participants as either completely adherent (n=9 64%) or mostly adherent (n=5, 36%).
- h. A majority of participants (n=6, 67%) exhibited no symptoms of depression. However, two participants (22%) exhibited minimal symptoms and one participant (11%) exhibited minor depression/mild major depression (Table 1).
- i. Likewise, a majority of participants (n=5, 56%) were observed to have no anxiety, while four participants (44%) exhibited mild anxiety. One participant screened positive for post-traumatic stress disorder (11%, Table 1).
- j. Most participants (n=8, 89%) reported high levels of social support whereas one participant (11%) reported only moderate social support (Table 1).
- k. High levels of conscientiousness were observed in eight participants (89%), high levels of emotional stability and openness to experiences were observed in 6 participants (67%), high levels of extraversion and agreeableness were observed in five participants (56%, Table 1).

Table 1. Characteristics of the study population, psychosocial factors and medication adherence.

**Participant Demographics (n=14)**

Caucasian	14 (100%)
Male	13 (93%)
≥1 comorbidity	9 (64%)

**Transplant and Adherence Background (n=14)**

Years since transplant (median (IQR))	8.5 (5-11)
Lost VCA graft	2 (14.3%)
Episodes of rejection (median (IQR))	5 (2-10)
Private insurance	10 (71%)
Indications of non-adherence	3 (21%)
Providers have discussed non-adherence	5 (36%)
Extent of adherence	
Completely	9 (64%)
Mostly	5 (36%)
Multi-drug immunosuppressive regimen	10 (71%)

**Psychosocial Factors (n=9)**

Depression	
No symptoms	6 (67%)
Minimal symptoms	2 (22%)
Minor depression/major depression, mild	1 (11%)
Major depression, moderately severe	0
Major depression, severe	0
Anxiety	
No anxiety	5 (56%)
Mild anxiety	4 (44%)
Moderate anxiety	0
Severe anxiety	0
Personality Traits (High levels)	
Emotional stability	6 (67%)
Extraversion	5 (56%)
Openness to experiences	6 (67%)
Agreeableness	5 (56%)
Conscientiousness	8 (89%)
Social support	
Moderate Support	1 (11%)
High Support	8 (89%)
Post-traumatic stress disorder	1 (11%)

Regarding Aim 3, given our limited sample size, the small prevalence of non-adherence in our study population, and limited pool of VCA recipient in the US (n=102), a biostatistician determined that it is not feasible to develop a risk prediction calculator to predict risk of medication non-adherence for VCA candidates at this time. Due to these factors we were unable to achieve aim 3 during the grant period.

**What opportunities for training and professional development has the project provided?**

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

Macey Henderson, an investigator on a K award providing uncompensated effort on this award, was able to present at a DOD investigator meeting on behalf of PI Dorry Segev. The analyst on this project, Sarah Rasmussen was able to present our findings from this study at the American Society of Reconstructive Transplantation, and the American Transplant Congress in 2017 and 2018.

**How were the results disseminated to communities of interest?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

The results of this study were presented as poster presentations at the American Society for Reconstructive Transplant in 2018 and the American Transplant Congress (ATC) in 2018 (psychosocial assessment only) and 2019 (adherence, transplant outcome, and psychosocial findings). These posters helped disseminate our findings to the transplant community, in particular ATC which is attended by transplant surgeons, professionals and researchers, most of whom specialize in thoracic or abdominal transplantation.

**What do you plan to do during the next reporting period to accomplish the goals?**

*If this is the final report, state “Nothing to Report.”*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

Nothing to report.

- 4. IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

**What was the impact on the development of the principal discipline(s) of the project?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

By identifying psychosocial factors prevalent among VCA recipients, this study contributes to the ongoing discussion regarding the importance of assessing psychosocial factors that may predict medication nonadherence.<sup>1,2</sup>

**What was the impact on other disciplines?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to report.

**What was the impact on technology transfer?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

**What was the impact on society beyond science and technology?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

VCA is a growing field, and assessing psychosocial factors and medication adherence in this population is an important step in improving VCA outcomes. Ultimately, VCA is a promising therapy and improving its outcomes will provide an important and lifechanging option for veterans, accident survivors, burn victims and amputees.

**5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

**Changes in approach and reasons for change**

We initially planned a single center study of VCA recipients, but given the small number of VCA recipients at our center expanded this study to Christine M. Kleinert Institute. This change was approved by HRPO. Furthermore, we were limited in our ability to execute Aim 3 of the grant due to the small number of eligible participants at our study sites and nationally. Therefore, we plan to prepare a manuscript characterizing the psychosocial factors and medication adherence among VCA recipients.

**Actual or anticipated problems or delays and actions or plans to resolve them**

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

Not applicable.

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Nothing to report.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

We expanded our study to include participants from Christine M Kleinert Institute (CMKI). This was approved by the IRB at CMKI on August 10 2018 and HRPO approval for this expansion was approved on October 15, 2018.

**Significant changes in use or care of vertebrate animals**

Nothing to report.

**Significant changes in use of biohazards and/or select agents**

Nothing to report.

**6. PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

- **Publications, conference papers, and presentations**

*Report only the major publication(s) resulting from the work under this award.*

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

We are preparing a manuscript characterizing medication adherence and psychosocial factors among VCA recipients, to be submitted to the American Journal of Transplantation.

**Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report

**Other publications, conference papers and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

Rasmussen S, Henderson M, Cooney C, Shores, JT, Lee WPA, Brandacher G, Segev D. "Psychosocial Factors Affecting Recipients of Vascularized Composite Allografts." The American Transplant Congress. Seattle WA, June 2017

Rasmussen S, Cooney C, Shores JT, Lee WPA, Segev D, Brandacher G, Henderson M. "Psychosocial Factors Affecting Recipients of Vascularized Composite Allografts." The American Society of Reconstructive Transplantation. Chicago IL, November 2018

Rasmussen S, Henderson M, Cooney C, Shores J, Lee WPA, Goldman E, Kaufman C, Segev D, Brandacher G. "Psychosocial Factors and Medication Adherence among Recipients of Vascularized Composite Allografts." The American Transplant Congress. Boston MA, June 2018

- **Website(s) or other Internet site(s)**

*List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

Nothing to report.

- **Technologies or techniques**

*Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.*

Nothing to report.

- **Inventions, patent applications, and/or licenses**

*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

Nothing to report.

- **Other Products**

*Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

#### Example:

Name: Mary Smith  
Project Role: Graduate Student  
Researcher Identifier (e.g. ORCID ID): 1234567  
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name:	Sarah Rasmussen
Project Role:	Research Data Analyst
Nearest person month worked:	5.28 CM
Contribution to Project:	Ms. Rasmussen participated in protocol development, study coordination, data collection, data analysis, data interpretation, and manuscript preparation

Name:	Xun Luo
Project Role:	Research Data Analyst
Nearest person month worked:	0.36 CM
Contribution to Project:	Dr. Luo participated in study design

Name:	Carisa Cooney
Project Role:	Co-Investigator
Nearest person month worked:	0.48 CM
Contribution to Project:	Ms. Cooney participated in study design and data interpretation

Name:	Macey Henderson
Project Role:	Co-Investigator
Nearest person month worked:	0.38 CM (uncompensated effort)
Contribution to Project:	Dr. Henderson participated in study design, study coordination, data interpretation, and manuscript preparation

Name: Gerald Brandacher  
Project Role: Co-Investigator  
Nearest person month worked: 0.36 CM  
Contribution to Project: Dr. Brandacher has participated in study design, data interpretation, and oversight of the study

Name: Dorry Segev  
Project Role: Principal Investigator  
Nearest person month worked: 0.96 CM  
Contribution to Project: Dr. Segev has directed all project activities including research design, protocol development, data analysis, data interpretation and manuscript preparation

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

Nothing to report.

**What other organizations were involved as partners?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

*Organization Name:*

*Location of Organization: (if foreign location list country)*

*Partner’s contribution to the project (identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Christine M. Kleinert Institute  
Louisville, KY  
Collaboration

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

**QUAD CHARTS:** *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

**9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

## REFERENCES:

1. Jowsey-Gregoire SG, Kumnig M, Morelon E, Moreno E, Petruzzo P, Seulin C. The Chauvet 2014 Meeting Report: Psychiatric and Psychosocial Evaluation and Outcomes of Upper Extremity Grafted Patients. *Transplantation*. 2016;100(7):1453-1459.
2. Kumnig M, Jowsey-Gregoire SG. Key psychosocial challenges in vascularized composite allotransplantation. *World journal of transplantation*. 2016;6(1):91-102.

## **Appendix I: Psychosocial Assessment**

### **Demographics**

1. Please indicate the highest level of education you have completed:
  - a. Less than high school
  - b. High school or GED
  - c. Associate's degree
  - d. Bachelor's degree
  - e. Graduate degree
  
2. Are you currently employed?
  - a. Yes, part time
  - b. Yes, full time
  - c. No
  - d. No, on disability
  - e. Retired
  
3. What is your combined annual household income?
  - a. \$0-19,999
  - b. \$20,000-39,999
  - c. \$40,000-59,000
  - d. \$60,000-79,999
  - e. \$80,000 - 99,999
  - f. \$100,000-119,999
  - g. \$120,000-139,999
  - h. \$140,000-159,999
  - i. >\$160,000
  
4. Is all or part of this from disability?
  - a. Yes
  - b. No
  
5. What is your marital status?
  - a. Single
  - b. Married
  - c. Co-habiting
  - d. Divorced

### **Generalized Anxiety Disorder 7-item Scale**

Over the last 2 weeks, how often had you been bothered by the following problems?

1. Feeling nervous, anxious or on edge
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
  
2. Not being able to stop or control worrying

- 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
3. Worrying too much about different things
- 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
4. Trouble relaxing
- 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
5. Being so restless that it is hard to sit still
- 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
6. Becoming easily annoyed or irritable
- 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
7. Feeling afraid as if something awful might happen
- 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day

### **Patient Health Questionnaire – 9**

Over the last 2 weeks, how often have you been bothered by any of the following problems?

- 1. Little interest or pleasure in doing things
  - 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
- 2. Feeling down, depressed or hopeless
  - 0. Not at all
  - 1. Several days
  - 2. More than half the days
  - 3. Nearly every day
- 3. Trouble falling or staying asleep, or sleeping too much
  - 0. Not at all
  - 1. Several days
  - 2. More than half the days

3. Nearly every day
4. Feeling tired or having little energy
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
5. Poor appetite or overeating
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
7. Trouble concentrating on things, such as reading the newspaper or watching television
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day
9. Thoughts that you would be better off dead or hurting yourself in some way
  0. Not at all
  1. Several days
  2. More than half the days
  3. Nearly every day

### **Ten Item Personality Inventory**

Here are a number of personality traits that may or may not apply to you. Please write a number next to each statement to indicate the extent to which you agree or disagree with that statement. You should rate the extent to which the pair of traits applies to you, even if one characteristic applies more strongly than the other

- 1 = Disagree strongly
- 2 = Disagree moderately
- 3 = Disagree a little
- 4 = Neither agree nor disagree
- 5 = Agree a little
- 6 = Agree moderately
- 7 = Agree strongly

I see myself as:

1. \_\_\_\_\_ Extraverted, enthusiastic.
2. \_\_\_\_\_ Critical, quarrelsome.
3. \_\_\_\_\_ Dependable, self-disciplined.
4. \_\_\_\_\_ Anxious, easily upset.
5. \_\_\_\_\_ Open to new experiences, complex.
6. \_\_\_\_\_ Reserved, quiet.
7. \_\_\_\_\_ Sympathetic, warm.
8. \_\_\_\_\_ Disorganized, careless.
9. \_\_\_\_\_ Calm, emotionally stable.
10. \_\_\_\_\_ Conventional, uncreative.

### **Primary Care PTSD Screen for DSM-5**

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you:

1. Have had nightmares about it or thought about it when you did not want to?  
YES / NO
2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?  
YES / NO
3. Were constantly on guard, watchful, or easily startled?  
YES / NO
4. Felt numb or detached from others, activities, or your surroundings?  
YES / NO

*Current research suggests that the results of the PC-PTSD should be considered "positive" if a patient answers "yes" to any three items.*

### **Multidimensional Scale of Perceived Social Support**

Instructions: We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement.

- 1 = Very Strongly Disagree  
2 = Strongly Disagree  
3 = Mildly Disagree  
4 = Neutral  
5 = Mildly Agree  
6 = Strongly Agree  
7 = Very Strongly Agree

1. \_\_\_\_\_ There is a special person who is around when I am in need.
2. \_\_\_\_\_ There is a special person with whom I can share joys and sorrows.
3. \_\_\_\_\_ My family really tried to help me.
4. \_\_\_\_\_ I get the emotional help & support I need from my family.
5. \_\_\_\_\_ I have a special person who is a real source of comfort to me.
6. \_\_\_\_\_ My friends really try to help me.
7. \_\_\_\_\_ I can count on my friends when things go wrong

8. \_\_\_\_\_ I can talk about my problems with my family
9. \_\_\_\_\_ I have friends with whom I can share my joys and sorrows.
10. \_\_\_\_\_ There is a special person in my life who cares about my feelings.
11. \_\_\_\_\_ My family is willing to help me make decisions
12. \_\_\_\_\_ I can talk about my problems with my friends.

## Appendix 2: Medication Adherence and Transplant Outcomes Abstraction Form

### Provider information

1. What is your role on the transplant team?
  - Surgeon
  - Coordinator
  - Nurse
  - Research
  - Other: Please describe

### Patient background and transplant information

2. Patient Race/Ethnicity: Click or tap here to enter text.
3. Transplant type (organ): Click or tap here to enter text.
4. Year of transplant: yyyy
5. Sex: Click or tap here to enter text.
6. Has the patient experienced loss of the transplanted VCA graft? Choose an item.
  - No
  - Yes
7. Number of episodes of rejection of the transplanted VCA graft  
(If no episodes, please enter "0"): Enter number here
  - a. How many of those episodes were:
    - i. Mild: Enter number here
    - ii. Acute: Enter number here
    - iii. Biopsy Proven: Enter number here

*Form continues on the next page*

## Immunosuppressive medication and adherence information

8. What is the patient's insurance status?
- Public insurance
  - Private insurance
  - Uninsured
9. Who pays for this patient's immunosuppressive medication?
- The patient's insurance
  - The transplant center
  - The patient
  - A research grant
10. Are there any indications that this patient is not adhering to their immunosuppressive medication regimen?
- No
  - Yes
11. Do you suspect that the patient is not adhering to their immunosuppressive medication regimen?
- No
  - Yes
12. If yes to numbers 10 and/or 11, please describe the indications that this patient is not adhering to their immunosuppressive medication regimen.
- Click or tap here to enter text. Textbox will expand if you have a long response.
13. If yes to numbers 10 and/or 11, have you noticed any of the following in this patient? Please mark all that apply.
- Erratic immunosuppression levels
    - Low immunosuppression levels
    - High immunosuppression levels
  - Frequent rashes
  - Patient resistant to having labs drawn
  - Rejection episode that is unresponsive to steroids (e.g. IV prednisone)

***Form continues on the next page***

14. Have you or a member of your clinical team ever discussed being non-adherent to immunosuppressive medications with this patient?
- Yes
  - No
15. If yes, approximately how many times have you discussed being non-adherent to immunosuppressive medications with this patient? *Enter number here.*
16. Overall, how would you rate the patient's medication adherence?
- Completely adherent
  - Mostly adherent
  - Somewhat adherent
  - Not at all adherent
17. Is this patient on a single- or multi-drug immunosuppression regimen?
- Single-drug
  - Multi-drug
18. Is there anything else you'd like us to know about immunosuppressive adherence in this patient?  
*Click or tap here to enter text. Text box will expand if you have a long response.*

***Form continues on the next page***

## Charlson Comorbidity Index

Please indicate if the patient has been diagnosed with any of these conditions.

1. Myocardial infarction or heart attack Choose an item.
2. Peripheral vascular disease such as intermittent claudication, acute arterial insufficiency, or thoracic or abdominal aneurysm Choose an item.
3. Cerebral vascular disease such as stroke or transient ischemic attack (mini stroke) Choose an item.
4. Dementia Choose an item.
5. Chronic lung disease Choose an item.
6. Rheumatological disease, such as lupus, connective tissue disease, or rheumatoid arthritis Choose an item.
7. Peptic ulcer disease Choose an item.
8. Diabetes Choose an item.
9. Diabetes with complications, such as retinopathy, neuropathy or nephropathy Choose an item.
10. Moderate or severe liver disease, such as cirrhosis, portal hypertension, or variceal bleeding Choose an item.
11. Metastatic cancer Choose an item.
12. Leukemia Choose an item.
13. Lymphoma Choose an item.
14. HIV Choose an item.
15. Disability Choose an item.
  - a. Visual impairment Choose an item.
  - b. Hearing impairment Choose an item.
  - c. Walking disability Choose an item.
  - d. Other disability Choose an item.
    - i. 1<sup>st</sup> other disability Click or tap here to enter text.
    - ii. 2<sup>nd</sup> other disability Click or tap here to enter text.
    - iii. 3<sup>rd</sup> other disability Click or tap here to enter text.
    - iv. 4<sup>th</sup> other disability Click or tap here to enter text.
    - v. 5<sup>th</sup> other disability Click or tap here to enter text.
16. Traumatic Brain Injury Choose an item.
17. Substance Abuse (alcohol, prescription drugs, or illicit drugs) Choose an item.
18. Anger management issues Choose an item.

*Form continues on the next page*

### **Contacting the patient:**

Have you discussed participating in his study with this patient? If yes, please put patient's contact info here

1. Patient Name: Click or tap here to enter text.
2. Patient Date of Birth: mm/dd/yyyy
3. Patient primary phone number: ( ) -
4. Patient alternative phone number: ( ) -