



American Society of Transplant Surgeons

May 1, 2008

James F. Burdick, M.D.
Director, Division of Transplantation
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Room 12C-06
Rockville, Maryland 20857

Re: Vascularized Composite Allografts: Request for Information

Dear Dr. Burdick:

The American Society of Transplant Surgeons is pleased to respond to the Request for Information as published in the March 3, 2008 Federal Register regarding vascularized composite allografts.

The ASTS supports inclusion of vascularized composite allografts within the definition of organs covered by regulations governing the Organ Procurement and Transplantation Network (OPTN) and would support adding them to the definition of human organs covered by the National Organ Transplant Act.

Because recovery of vascularized composite allografts (e.g. hand, face) from deceased donors all entail direct interaction with Organ Procurement Organizations (OPOs) in connection with recovery of solid organs, we believe it is appropriate that the OPTN's regulatory oversight be extended to vascularized composite allografts.

Like all other transplantation, composite tissue allotransplantation (CTA) has the capacity to transform the lives of patients, for the better and for the worse. It is that duality that mandates CTA be performed in an area prepared and equipped to respond to the inevitable contingencies related to surgical and infectious complications, immunosuppression, social and financial stresses, and the other complexities accompanying other transplant procedures. As such, centers moving forward with CTA should demonstrate the same depth and breadth of services currently mandated by the Transplant Final Rule for solid organ transplantation. Failure to do so will set this burgeoning field up for serious and very public failure that will deprive many future patients the potential benefits of CTA.

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The intent of creating standards for vascularized composite allografts under the definition of Organs under the Final Rule as well as under the definition of Human Organs under section 301 of NOTA adds to the armamentarium necessary to provide the highest quality practice possible with consistency, safety and professionalism.

As an experimental field, we recognize that this area is in its initial stages but that it will likely experience a growth period in the near future. It is for that and other reasons that the ASTS supports the creation of standards at this point in time. We would like this field to develop with a scholarly approach, not so much to promote an academic development in this field, but rather to insure the best and most sustainable outcomes for potential patients. We believe that standards enhance protection to our patients, the community and our discipline. On the contrary, a field without an entity exercising responsibility for making things work and improving performance could directly and indirectly affect our patients, our practice and transplantation services in the United States.

Specific points and advantages,

- 1) Vascularized composite graft should be included under the definition of Organs under the Final Rule as well as under the definition of Human Organs under section 301 of NOTA
- 2) The definition could be broad describing the features of the allografts without listing particular body parts. Shared characteristics could include (a) a vascularized allograft containing multiple tissue types, (b) recovered from a human donor as an anatomical/structural unit, (c) transplanted into a human recipient as an anatomical/structural unit, (d) minimally manipulated, as defined by FDA in Title 21 CFR 1271.3, (e) not combined with another article such as a device, (f) used fresh and not cryopreserved, (g) susceptible to ischemia and therefore, not stored temporarily, (h) susceptible to allograft rejection which requires immunosuppression.
- 3) OPTN oversight would define major federal regulation process
- 4) The organ-specific experts have a key role in establishing membership criteria and other rules in the policies
- 5) The relationship with the OPO's would be facilitated
- 6) Allocation could be over a wide area, allowing easy search for appropriate allocation
- 7) It would provide assurance that all programs are following similar rules
- 8) It would be helpful when questions in the government or the public arise
- 9) The field could be advanced by these factors and the committee process and data reporting
- 10) The acceptance from the public for donation of vascularized composite grafts could be facilitated
- 11) Public transparency will enhance the field.

Please feel free to contact me or Katrina Crist, ASTS Executive Director, if you have questions or need further information.

Sincerely,



Goran B. Klintmalm, MD, PhD, FACS
ASTS President