December 12, 2006

Board of Directors
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Re: Public Comment concerning Modifications to Data Elements on UNet Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee)

Dear UNOS/OPTN Board of Directors:

The American Society of Transplantation (AST) and American Society of Transplant Surgeons (ASTS) recognize and appreciate the work of the Policy Oversight Committee (POC), in particular, and UNOS in general, for their ongoing efforts to reduce the burden of data submission for all transplant programs. We have worked closely with POC and we are very pleased with progress to date.

However, we are extremely concerned that there is continuing confusion about the Principles of Data Submission (the "Principles") to be used to review the data submission requirements to be imposed on Transplant Centers in the future. We are equally concerned that the views expressed by the AST and the ASTS regarding the Principles apparently have not been fully considered by the UNOS/OPTN Board; in fact, there appears to be considerable confusion about what, if any, Principles actually obtained Board approval.

The "Modifications to Data Elements on the Recipient Follow-up Form" (the "Notice") that is currently subject to comment illustrates the potential risk of the lack of any clear Principles or disciplined process for applying those Principles. In our view, a number of the data submission requirements described in the Notice are not supported by any of the Principles that have been proposed. This is not a propitious start to the goal of maintaining data submission requirements at reasonable levels.

More specifically, in our view there are four issues that require further consideration. First, and perhaps most importantly, we believe that the Principles set forth below should be clearly approved by the Board and a process of applying the Principles should be discussed by the Board with some specificity. Second, both in the context of the current Notice and in a broader context, the timeframe for data collection should be clearly established. Third, the data elements described in the Notice should be subject to rigorous application of the Principles. Fourth, the

extent of proposed Immunosuppression and Malignancy data should be reconsidered and should be subject to rigorous application of the Principles.

We will comment on each issue individually:

1. Approval of the Principles of Data Submission:

Preliminarily, we would like to review the history of the development of the Principles. Initially, in 2005, the UNOS Board and leadership recommended three principles for determining the utility of a data element. Under these principles, transplant centers would be required to submit data if such data was used for:

1) policy development
2) performance assessment
3) organ distribution

In developing its recommendations for reduction of data elements, the Joint Task Force of the AST and the ASTS were specifically invited to provide this information in order to accelerate the data reduction process. The AST/ASTS Joint Task Force expanded the list of principles that would authorize data collection and presented the following to UNOS/OPTN in Boston in October, 2005:

1) The cost of data collection and submission from Transplant Centers to the OPTN must be reimbursed from a readily identified source.
2) Transplant Centers must provide sufficient data to the OPTN to assure that the OPTN can determine Transplant Center compliance with all applicable regulations and policies.
3) Transplant Centers must provide sufficient data so that the OPTN can determine risk-adjusted center-specific outcomes.
4) Transplant Centers must provide sufficient data to permit the OPTN to develop appropriate allocation policy.
5) Data collected and submitted by the Transplant Centers may differ in nature and character for specific populations, forming exceptions to Guiding Principles 1-4 (above) (Pediatrics, Living Donors).

The UNOS/OPTN Board reviewed these principles at the Strategic Planning Retreat and approved them.

The POC drafted a different set of Principles (the "POC Principles") in developing its recommendations for data reduction, which is contained in a document dated December, 2005 and revised in February, 2006. The POC Principles authorize data collection where necessary for:

1) Allocation of Organs
2) Policy Compliance
3) Contractual obligations (including HRSA, SRTR, CMS, USRDS)
4) Institutional Performance
5) Policy development
6) Patient Care/Safety

After extensive study and debate, the AST and ASTS refined the Principles and sent the revised Principles (AST/ASTS Principles) on June 12, 2006 to the POC as a response to a request for public comment on the final data reduction notice. The AST/ASTS Principles differ from the POC Principles insofar as it would allow exceptions to the Principles under certain circumstances, so long as the need for the exceptions are clearly articulated and subject to POC and Board approval and to public comment. The AST and ASTS further added the following additional Principle:

> All future data requests by OPTN committees must be justified in the context of the above guiding principles. Any new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN and will be subject to public comment.

While the POC Principles were presented in POC reports to the Board of Directors in March and June, 2006, the POC Principles in their entirety were never submitted for a vote of approval by the Board. The only Principle voted on by the Board of Directors was the POC Principle 6, which would authorize data collection in the interests of "patient care/safety." The Board specifically limited the definition for "patient care/safety" as follows: "Resolved, that the OPTN will, on rare occasions, collect limited but necessary data regarding patient safety in areas in which the OPTN has a unique perspective or responsibility for monitoring patient safety, which may include requirements regarding such from the OPTN contract or the OPTN Final Rule."

Thus, there has been an evolution of the proposed Principles over time. There are several non-controversial principles that all groups have agreed upon—that data collection is to be authorized for the purpose of policy compliance and development, performance assessment, and organ allocation. However, the Principles in their entirety were never formally approved by the UNOS/OPTN Board and remain controversial in a number of respects.

First, the POC has not included or commented on several of the Principles proposed by ASTS and AST, specifically:

- That the reasonable cost of data collected and submitted by Transplant Centers to the OPTN that do not meet guiding principles be reimbursed from a readily identified source;
- That exceptions be made only under certain circumstances and for reasons that are clearly articulated; and
- That all future data requests by OPTN committees be justified in the context of the Principles.

ASTS and AST strongly believe that adoption of these Principles and a clear process for approving any new data reporting requirements are necessary to assure that the data burden does not again grow to unmanageable proportions and as a means to improve the quality of data reported.

Second, ASTS and AST have concerns about POC Principle 3, which would authorize data collection necessary to fulfill the OPTN's contractual obligations. In justifying this Principle, the POC states:

> By contract, the OPTN is obliged to provide all or some of its data to other organizations, including HRSA, SRTR, CMS and USRDS. This arrangement strongly dictates the scope of data collection by OPTN.

This suggests that the OPTN could enter into a contract with some organization to collect data that it would not ordinarily collect. We request a clarification of the scope of this principle.

Third, the AST and ASTS appreciates the limitations upon the POC Principle that would authorize additional data collection when required by patient safety concerns, (POC Principle 6 as modified and adopted by the Board), but reiterates its request that all data elements justified by this Principle (as well as any other principle) be specifically approved by both the POC and the Board of Directors and subject to public comment.

Finally, the AST and ASTS continues to oppose the requirements for submission of information about immunosuppression insofar as it does not meet any of the proposed principles. In addition, the current requests for malignancy data seem to exceed the need for assuring the safety of recipients.

Based on this information, we propose that the UNOS/OPTN Board of Directors formally approve the following Principles for Data Collection:

1. *Transplant Centers must provide sufficient data to OPTN to allow it to:*
   a) *Develop policy and regulations to allocate organs for transplant*
   b) *Determine if Transplant Centers are complying with policy*
   c) *Determine Center-specific performance*
   d) *Ensure patient safety when no alternative sources of data exist*
2. *OPTN will provide appropriate data to other organizations under contract but cannot enter into contracts that would compel them to collect data beyond that permitted above.*
3. *The reasonable cost of data collected and submitted by Transplant Centers to the OPTN that do not meet these two guiding principles must be reimbursed from a readily identified source.*
4. *Data collected and submitted by Transplant Centers to the OPTN may differ in nature and character for specific populations, forming exceptions to Guiding Principles above (e.g. Pediatrics, Living Donors). For these exceptions to the foregoing principles, alternative sources of information must be developed and supported, duplication of existing efforts (e.g. registries) avoided and sample data collection considered. The need and purpose of any such exceptions must be clearly articulated and subject to Policy Oversight Committee and Board approval and public comment.*
5. *All future data requests by OPTN committees must be justified in the context of the above guiding principles. And new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN and be subject to public comment.*

2. Rationale for extending any data collection beyond three years:

During its deliberations on the data reduction project, the POC considered the post-transplant period during which data collection would be required, frequently framing the discussions in terms of a three to five year post-transplant period for data collection. It appears that the POC now supports extending data collection for five years post-transplant, despite the recommendation

of the AST and ASTS, which recommended a time limit of three years for virtually all data elements. Moreover, the current Notice would require data collection even beyond five years.

Data collection extending beyond three years does not appear to be justified either by the Principles developed by the AST and ASTS or by those developed by the POC. Policy compliance and development (POC Principles 2 and 5, respectively) focus on requirements that must be met at the time of listing or transplantation, and not five years post-transplant –or even beyond, in the case of the current Notice. Determination of institutional performance (POC Principle 4) is currently based on outcomes determined at 3 months, one year and **three years** and not beyond that. We are not aware of any current OPTN contractual obligations (POC Principle 3) that require data collection beyond three years, nor are such continuing data requirements authorized by patient safety concerns (POC Principle 6). While recent proposals for organ allocation may depend on longer term graft or patient survivals, those proposals relate to only two data elements (i.e. graft and patient graft survival), and if such proposals are adopted, data collection requirements could be extended an additional two years for these data elements only.

For these reasons, we propose that the Board of Directors limit the bulk of data collection to three years post transplantation, not five.

3. Basis for retention of proposed elements described in the proposal.

The POC seems to have provided some latitude to the organ-specific committees in determining what data elements to include for long-term data submissions, although they have clearly challenged those committees to adhere to their proposed Principles. While the requested data elements have been substantially reduced as a result, we believe that a number of the organ-specific committee data elements are not justified in terms of the Principles. For example, the Liver follow-up form requests contributory causes of graft failure without a primary cause. How does this adhere to the principles? The thoracic follow-up form requests detailed information about renal function: What Principle does this address and how?

Based on this information, we propose that the UNOS/OPTN Board of Directors request detailed justification for every individual data element requested by the POC or the organ-specific committees and approve each element individually.

4. Immunosuppression and Malignancy data.

The AST and ASTS did not support the collection of any data concerning immunosuppression medications. While we appreciate the marked reduction in the amount of data requested, we still do not understand how they are justified by any of the proposed principles. Furthermore, while we support the inclusion of malignancy data that might reflect donor-derived tumors (which would be important for informing recipients of other organs from the same donor), we also fail to understand how the extensive data requested by POC are justified by any of proposed principles. The association of organ transplant immunosuppression and acquired malignancies is well known. Moreover, existing registries are already the source of well-characterized data.

Based on this information, we propose that the UNOS/OPTN Board of Directors reconsider the amount and extent of data recommended by POC concerning malignancy and immunosuppression.

The AST and ASTS appreciate the opportunity to provide these comments, and look forward to resolving these issues in a manner that appropriately balances the need for data collection with the administrative burden imposed on transplant centers.

If you have any questions regarding these comments, or if we can be of any further assistance as this endeavor moves forward, please do not hesitate to contact us.

Sincerely yours,

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