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MEMORANDUM

To: Dr. Carl Berg, UNOS President
Mr. Brian Shepard, UNOS CEO

From: Ms. Leslie Clark, Executive Director
American Society of Transplantation (AST)

RE: AST Comments on OPTN Policy Proposals

Date: December 5, 2014

On behalf of the American Society of Transplantation Board of Directors, I am attaching the Society's comments on the eighteen OPTN policy proposals currently out for public comment.

The AST has reviewed and provided comments on seventeen proposals. We are supportive of proposals 5, 6, 7, 14, 15, 16, 17 and proposals 1, 2, 3, 4, 8, 9, 12, 13, and 18 with consideration of the enclosed comments. We are not supportive of proposal 10 as currently drafted and our comments provide the rationale.

Please let me know if there are any questions about our comments. Thank you for the opportunity to provide feedback on these policy proposals.

Cc: AST Board of Directors
Dr. Yolanda Becker, AST's UNOS Board Representative

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AMERICAN TRANSPLANT CONGRESS 2015

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Proposal 1: Informed Consent for Kidney Paired Donation
We find the proposal timely and well written. The AST supports this proposal, with the following recommended additions (in italics) to address the lack of information about outcomes, which is significant for donors in KPD:

13.4.C Additional Requirements for KPD Donors

For any KPD exchange, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of *all* of the following:
1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match, *and will get limited information about this match, within the bounds of HIPAA.*

11. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes, *and that the donor may not learn much about outcomes at all for their actual recipient*.

Proposal 2: Proposal for the Definition of Pancreas Graft Failure
The AST supports this proposal. It is important that pancreas graft failure should have its own organ-specific definition and the proposal addresses this need.

We agree with the current proposal where death is included in the definition of a pancreas graft failure and would like to suggest that the committee consider including a statement of clarification that states the insulin use (units/kg/day) is calculated by combining the total long-acting and short-acting insulin amounts used in one day.

We believe the policy language should be implemented as soon as possible. We agree that additional data fields will greatly enhance our ability to develop a standardized set of metrics to evaluate the status of pancreas graft outcomes as well as patient outcomes following pancreas transplantation, and provide information that can be used to educate the community. However, this critical policy, providing the language for the definition of pancreas graft failure, should be shared and implemented as soon as possible.

As new fields will be added to the pancreas forms, the committee should consider adding a field to collect data on other oral agents that the pancreas transplant recipient (without graft failure) may be using to manage insulin resistance.

Proposal 3: Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates
The AST believes this is a major step forward in helping define the candidates that will exhibit the most benefit from lung transplantation. We offer the following comments:

1. We believe that it is extremely important to define the **indication** for ECMO. This will better determine waitlist urgency and post-transplant benefit. One idea for capturing indication would be the following:
    a. **Indication**
        i. Hypercapneic

ii. Hypoxic
iii. Hemodynamic instability
iv. Other_____

However, we worry that a categorized indication alone, might not clearly represent the severity of illness and might not help us determine the true effect that mechanical support has on waitlist urgency and post-transplant benefit. Therefore, we believe that including information about ABG, O2 (L/flow) or % FiO2 is important.

b. ABG/VBG Measurements prior to initiation of ECMO/MV
    i. pH with Time/Date and source (venous/arterial)
    ii. pCO2 with Time/Date and source (venous/arterial)
    iii. PaO2 with Time/Date and source (venous/arterial)
    iv. FiO2 or O2 (and flow rate if applicable) with Time/Date.

2. We agree that ambulation status is an important variable for ECMO and mechanically ventilated patients. From the proposal, it is unclear how ambulation will be defined. We recommend collecting additional information if the patient is declared ambulatory (Y/N). We prefer a **continuous variable** if possible, but other consideration could include:
    a. Dichotomous Variable
        i. < 100 feet
        ii. >=100feet
    b. Categorical Variable
        i. < 50 feet
        ii. 50-100 feet
        iii. 100-300 feet
        iv. >=300 feet

    In addition, we believe that this information should be dated and updated **at least every 2 weeks.** Another variable that may be useful is **tracheostomy** at time of transplant Y/N (if Y, time/date of trach placement).

3. We agree that it is important to capture all instances in which the candidate was supported by a mechanical support device throughout their time on the waitlist. We would recommend not only collecting the **DATES** of these procedures but the **TIME** of day that the patient was placed on these support devices. This will help us determine the sequence of starting and stopping support. In addition, data collection should reflect if different modalities that were started or stopped **more than once**. Additional variables that may be important to collect for patients while they are mechanical support are the use of **1) paralytics, 3) inotropes and 3) ultrafiltration with ECMO.**
    a. **Start Date and Time (1st occurrence)**
        i. V-V ecmo
        ii. V-A ecmo
        iii. Mechanical ventilation start

iv. Paralytic
v. Inotrope
vi. UF on ECMO

b. **End date/transplant date/or death on waitlist date and time (1st occurrence)**
   i. V-V ecmo
   ii. V-A ecmo
   iii. Mechanical ventilation start
   iv. Paralytic
   v. Inotrope
   vi. UF on ECMO
c. **Start Date and time (2nd occurrence)**
   i. V-V ecmo
   ii. V-A ecmo
   iii. Mechanical ventilation start
   iv. Paralytic
   v. Inotrope
   vi. UF on ECMO
d. **End date/transplant date/or death on waitlist (2nd occurrence)**
   i. V-V ecmo
   ii. V-A ecmo
   iii. Mechanical ventilation start
   iv. Paralytic
   v. Inotrope
   vi. UF on ECMO
e. etc

4. In addition to understanding how pre-transplant mechanical support affects post-transplant survival, we believe that it will be important to capture common and **serious complications**. We understand that this would most likely not be feasible for data collection on the TCR, but recommend considering the following variable for future modifications of the TRR.
   a. Complications
      i. ECMO after lung transplantation Y/N; if Y end date and time
      ii. PGD
      iii. HIT
      iv. Bleeding
      v. Renal Failure/Dialysis
      vi. Gas Embolism
      vii. Bronchial Anastomosis stenosis/IRI
      viii. Thrombocytopenia
      ix. Infection/Sepsis
      x. MOF
      xi. Thrombosis

xii. Ischemic
    1. Cardiac
    2. Limb
    3. Stroke

xiii. Technical

    1. ECMO pump failure
    2. Console failure
    3. Oxygenator failure
    4. System change

xiii. Pump Oxygenator type
xiv. Other

5. We also believe that the site of cannulation drainage and infusion is important to collect as has significant implications for severity of disease, post-op recovery (if applicable) and rehabilitation.
    a. Site of Cannulation drainage/infusion
        i. Venous return
            1. Femoral vein
            2. right internal jugular vein
            3. left internal jugular vein
            4. right atrium
            5. other
        ii. oxygenated return
            1. femoral vein
            2. RIJ (single cannula e.g. Avalon)
            3. RIJ
            4. femoral artery
            5. axillary artery
            6. aorta
            7. right atrium
6. Finally, AST is concerned "that the variability in these parameters (flow rates, sweep gas flow rates and fraction of delivered oxygen) driven by physiological changes would not be adequately or accurately captured with the periodic data reporting required for waitlist candidates." However, we believe that it might be helpful to capture these variables at the time of transplant. This may help provide additional information about the severity of the patient's disease at the time of transplant and may help in determining urgency and benefit in future models.

7. We would like to further comment that the burden here will be on the center to collect the data-while we feel this is very important, it also must be realized the work that will need to be done by someone at each center. The saving grace is that the number of ECMO lung transplant

candidate patients will be only a fraction of total cases. When this type of data collection has been suggested in the past in UNOS deliberations, transplant center appetite for more work was limited, and the only way in which efforts were successful were when HHS and DOT mandated the data be collected. Unfortunately, if we leave this voluntary the quality of data will suffer from missingness.

Proposal 4: Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)
The AST supports this proposal overall, but a separate policy is needed to address living donation in VCA.

Living donation for VCA recipients is an experimental procedure, with a dearth of published cases. Potential cases should get input and support from the transplant center's IRB and ethics committees. OPTN policies for LD VCA merit a separate, rigorous review prior to development and implementation. It is premature for VCA proposals to encompass LD. Instead it is recommended that policy development proceed in the stepwise fashion that OPTN/UNOS have employed in the development of other LD policy. Namely, policies were initially proposed and approved for kidney donors several years ago and now, we understand, have been expanded (under proposals out for public comment in Spring 2014) to encompass liver, pancreas, intestine, and lung donors. Similarly, plans should be made to build OPTN policy governing all LD VCAs (rather than include it in the current proposed VCA policies). LD VCAs should be removed from the current VCA policy proposals.

While the concept of policy from OPTN to guide LD VCA care is laudable (see p 14, "Expected Impact on Living Donors or Living Donation"), it is premature to fold this (hypothetical) population into policies guiding solid organ donors, policies that were developed based on known care needs, risks, and outcomes for these specific populations. Issues affecting VCA-LD evaluation, education, decision-making, and care are as yet poorly characterized and may in fact vary enormously even with the 'LD VCA' label because VCA transplantation encompasses a heterogeneous array of tissues/organs. It is highly likely that uterine donors have different needs than the (seemingly unlikely, but apparently possible) LD hand donor. Existing OPTN policies (e.g., those for living kidney donors now being expanded to encompass other solid organ living donors) would be inadequate and inappropriate when applied to certain types of VCA donors. It would be inaccurate to inform a hand donor, for example, of a "possibility" of a lifestyle change or of "potential" insurability problems. This means that there are no policy requirements in place or proposed that would be adequate for the VCA-LD.

We suggest OPTN LD policy for VCA LD reinforce general ethical principles, and professional societies including AST continue to support open dialogue, discussion and deliberation of factors guiding VCA transplantation (including LD). We strongly suggest the formation of a Joint Societies Work Group which, like the Work Groups that generated recommendations for the current OPTN policy concerning LDs, would work to develop appropriate recommendations for OPTN policy concerning VCA-LDs.

Proposal 5: Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs)
The AST fully supports the proposal as written. As VCAs are performed in greater numbers it is important to begin collecting data to determine best practices and ensure patient safety.

Proposal 6: Improving the OPTN Policy Development Process
The AST supports this proposal.

Proposal 7: Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)
The AST supports the phase II proposal. Overall, the current proposal adds valuable considerations that are expected to improve the histocompatibility laboratories management and performance.

Proposal 8: Proposal to Establish a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations
As currently written, the AST opposes this proposal. Not everyone falls under CMS guidelines and it is important for UNOS to align with CMS. The establishment of a QAPI standard within OPTN policy, while well-intended, is almost certain to lead to serious unintended consequences, and ignores the history of duplicative and conflicting transplant policy. The implementation of this policy as proposed puts us on track for more problems in misalignment between CMS and OPTN requirements. As happened with ABO verification requirements, establishing separate CMS and OPTN rules for QAPI programs will inevitably lead to increased costs of compliance to transplant centers as they bounce back and forth between two sets of rules (and more significantly, multiple constantly-changing surveyor interpretations). It will further increase the cost of survey for UNOS, which costs are passed on to transplant centers. All these additional burdens will occur without any reason to expect any improvement in quality or patient safety.

The AST is supportive of a high quality program with QAPI processes but wants to make sure a second quality process does not create an undue burden on the institutions. It is recommended that the policy be changed to reflect the following: If an institution operates under CMS standards, and is meeting those standards, then it is also meeting UNOS standards. If the institution is not operating under CMS standards, then it should have a QAPI plan in place that matches CMS standards.

The AST would support the QAPI policy if a crosswalk is done between CMS standards and the proposed UNOS regulations, to ensure these are in agreement with each other.

Proposal 9: Definition of a Transplant Hospital
The AST generally supports this proposal. However, the proposed requirement for geographic continuity as proposed is too strict and does not allow for the potential reasonable footprint of hospitals. Ideally, this provision should be removed as a single provider number, single governance, unified medical and nursing staff and a unified quality assurance plan and oversight should be sufficient to regard the facility as a transplant hospital. Alternatively, and given that quality of care received is inextricably linked to other services that are available within the confines of a hospital building(s) (ancillary services, on-site physician availability, O.R.s, equipment, etc…) this provision should be modified to a less stringent standard, such as locations no more than a few miles apart.

Proposal 10: Proposal to Implement Pre-Transplant Performance Review by the Membership and Professional Standards Committee
The American Society on Transplantation (AST) agrees with the Membership and Professional Standards Committee of UNOS that an over-reliance on post-transplant outcomes may lead to risk aversion on the part of transplant centers and thereby reduce access to solid organ transplants for patients deemed to be higher risk. Therefore the AST supports the concept of evaluating the pre-transplant performance of solid organ transplant programs as a means of providing a fuller assessment of quality, however, the proposal as written raises many concerns and in its current form cannot be supported by the AST.

The AST has some specific concerns as the CPM does not appear to take into account the heterogeneity of DSA geography; some states have a single DSA and some cities have multiple DSAs. Two transplant programs with the same CPM and with the same geography-adjusted transplant rates (DSA-based for both kidney and liver, page 12) could actually have different acceptance performance because of different import ischemic times. A program with a geographically large state-wide DSA has to import with longer ischemic times so its CPM may underestimate its performance when compared to programs commonly importing with shorter ischemic times. We are concerned that performance differences between programs in DSA-rich and DSA-poor areas will not be reflected in the CPM.

In regards to the proposal for monitoring kidney transplant programs, the AST has some specific concerns.

1. Figure 2 on page 4 of the proposal document shows that only 16 of 239 kidney transplant programs modeled would have Composite Pre-transplant metric (CPM) above 1.5. While the AST acknowledges the importance of identifying transplant programs whose performance deviates in a significantly negative fashion, the society is concerned that the proposed approach, which will identify 16 under-performing kidney transplant programs, will have unintended negative consequences (see below) on the performance of the 223 well-performing transplant programs that will outstrip the proposed benefit from this policy initiative and result in a worse overall experience for the transplant recipient population at large.

2. In an environment where the demand for organs so vastly outstrips supply – regardless of performance metrics deserving patients will never receive a transplant due to lack of organ availability – the AST believes a better approach is to remove disincentives to organ utilization and thereby first approach this issue by eliminating organ wastage. Therefore the AST looks forward to seeing data on the outcome of regional sharing of higher KDPI kidneys to assess if this result in higher recovery rates of said organs in organ procurement organizations (OPO) that heretofore have not recovered these organs. Moreover despite that Scientific Registry of Transplant Recipients (SRTR) protestations to the contrary, the AST does not believe that assurances that utilization of these kidneys is accounted for in a center's risk adjustment is sufficient to encourage appropriate risk taking on the part of a kidney transplant program, therefore the AST encourages the development of novel approaches to this issue. Such approaches might include: providing a survival outcome score for kidneys based upon KDPI quintiles, only reporting patient survival for recipients over the age of 70 who receive kidneys KDPI 0.86 and above, or only reporting patient and graft survivals normalized to the median patient and organ recovered in the transplant programs home OPO.

3. Geography adjust transplant rates: It is stated the C- Statistic of the model to discriminate between who is likely to receive a kidney transplant and who is not is 0.63. The discriminative power of this model is too low to be used for identifying programs for MPSC action. The AST suggests evaluating whether or not the addition of dialysis time and diabetic status (in effect adding it to the candidate age and previous transplantation status already factored in) I.E. adding EPTS would improve the kidney recipient model (page12).

   Moreover, the supply demand ratio is calculated as the number donors recovered over the number of waitlisted candidates. By choosing to include all recovered organs – SCD, ECD and DCD into the model, it ignores that in fact there are wide regional differences in ECD and DCD

recovery. Therefore, in a region where recovery of these organs is low, the supply will be viewed as low and therefore a program may be transplanting at an acceptable rate but with organs of better than expected outcomes. In this scenario, there is no incentive for transplant programs to increase the repertoire of organs accepted and no incentive for OPO to be more aggressive in organ recovery.

4. Geography adjust transplant rates: Including both active and inactive patients leads into the demand side of the equation may result in a scenario where deserving patients are not listed because they will result in a lower transplant rate. For example, patients needing weight loss or cancer-free survival may not initially be placed on the waiting list. While some will find their way back on, others run the risk of being "forgotten."

5. Living and deceased donors should be evaluated separately. Point number 3 on page 17 states:

   > "Kidney programs that perform a high percentage of living donor transplants tend to be more selective in accepting deceased donor offers. Excluding living donor transplants would have a disproportionate and unfair effect on such programs.

   On the contrary, the AST believes that programs doing a large volume of living donors – financially advantageous for the transplant center – should not be absolved from the fiduciary responsibility they have to make proper and efficient utilization of a national resource, deceased donor organs.

6. The AST is very concerned that this new metric to evaluate transplant program performance, like other metrics before it, will be coopted by the insurance industry and various for profit rating agency to assign titles such as "center of excellence" and "top performing". This will result in both the loss of the intended value of this metric for the MPSC and transplant programs "studying for the test" to curry favor with rating agencies. The AST wishes to see policy language expressly forbidding such information from being made public and penalties assessed for the both the intentional publication for self-promotion by a well performing program as well as the malevolent dissemination of a trouble program's data by a competitor program.

For patients with end-stage renal disease, the AST's overarching concern is that these changes could have *significant and serious unintended consequences* because they will likely lead to kidney programs changing practice patterns in a manner that does not benefit patients. The AST requests that the MPSC consider the impact that these changes could have for patients and weigh those outcomes against the benefits of having a more complete picture of pre and post-transplant outcomes to assess and discipline a few transplant programs.

The AST is also concerned about a number of aspects regarding the CPM metric in evaluating the performance of liver transplant programs:

1. Implementation of the CPM may inadvertently lead to risk aversion by liver transplant programs in not listing patients until they are much more critically ill with MELD scores > 30 in many regions. Thus patients with MELD scores lower than this (20-30) – a large percentage of the ESLD

population - may not get listed by centers to avoid the wait-list death penalty under the CPM calculation and thus not be offered or have access to organs. In the current system, most centers even in high MELD regions will list patients with MELD 20-30 as they might be offered an ECD liver transplant or be candidates for living donation. Thus, the CPM measure might reduce these listings and potentially disadvantage "lower" MELD patients by limiting their access to transplantation. Perhaps removing waitlist mortality as a measure and just using organ acceptance rates and transplant rates as measures would be more suitable and minimize significant practice changes that could disadvantage patients.

2. The AST believes that metrics incorporating pre- and post-transplant measures together might lead to a better assessment of liver transplant performance than each individually. They are very much tied together clinically as patients are sicker going into and coming out of the liver transplantation procedure.

Finally, while the proposal clearly states that the CPM results will be strictly accessible only between the program and the Performance Analysis and Improvement Subcommittee of the MPSC, the AST is concerned about the potential for the data to become public which could further directly affect the centers and their payors. The AST hopes that every measure would be taken to ensure that confidentiality is protected.

Proposal 12: Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act
The AST supports this proposal with a request for the following considerations:

Policy 2.7:
There should be some additional language similar to Policy 5.6 (Blood Type Verification upon Receipt) for HIV positive organs - basically a secondary verification and documentation of this verification that both the donor and recipient are HIV positive. This is a critical patient safety step.

Policy 15.3:
Should read "regarding the **use** ~~recovery~~ of organs from individuals known to be infected with HIV." The transplant center is not recovering the organs (the OPO is) but is instead using the organ.

Additional policy modifications are needed to the current Policy 15.3 (to be 15.4):
Current policy 15.3 (which requires obtaining specific informed consent from the recipient any time that…) reads: "The deceased donor has a known medical condition that may be transmissible to the recipient, with the exception of HIV, which must be handled according to Policy 2.7: HIV Screening of Potential Deceased Donors." Proposed policy should be as follows: "The deceased donor has a known medical condition that may be transmissible to the recipient, ~~with the exception of~~ **including** HIV~~, which must be handled according to Policy 2.7: HIV Screening of Potential Deceased Donors~~."

- Expected Impact on Living Donors or Living Donation: "It is anticipated that living donors will be included in the research protocols being developed by the NIH. However, before removing HIV from the exclusion criteria listed in Table 14-2 (Requirements for Living Kidney Donor Medical Evaluations) the group will seek input from the Living Donor Committee and the transplant community."

HIV infection is associated with a higher risk of intrinsic kidney disease. We feel that including discussion of living donation is outside the intent of the act and should be reviewed more carefully before being included in a UNOS policy, regardless of the recommendations for research. Just as overt hypertension

and diabetes are contraindications to living donation, HIV infection may have long term consequences to the health of a kidney donor.

Proposal 13: Proposal to Allow Collective Patient and Wait Time Transfers
The AST supports this proposal. We are in agreement with the current proposal suggestion that "the accepting transplant program must develop and implement a plan" for immediate review and designation of appropriate candidate waiting list status and provide an expected date for completing full evaluations. Since the number of patients being transferred may vary and the resources may vary by transplant site, it is not possible to provide a hard deadline.

In the current proposal it states that the accepting transplant program accepts responsibility "for patient notification and management according to all applicable OPTN Policies and Bylaws." In response to this specific issue, we would ask the committee to consider if the policy should outline the specifics of this requirement. For example, the policy can state "each patient must receive a letter within 'xx' days regarding their waiting list status and what the expectations are to become active a the accepting transplant program."

Proposal 14: Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18
The AST supports this proposal.

Proposal 15: Policy Rewrite Parking Lot "Quick Fixes"
The AST supports this proposal.

Proposal 16: Clarification of Multi-Organ Policies
The AST supports the entire group of recommended changes put forth in this proposal. It will clarify current policies related to multi-organ transplants. The changes add clarifications to the current policies.

Proposal 17: Proposal to Clarify Definition of Organ Transplant and Transplant Date
The AST supports this proposal as providing needed clarification to the policy requirements.

Proposal 18: Proposal to Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy
The AST finds this proposal, in general, to be sound and practical, but would like to have the following comments addressed before committing to full support:

- *Page 3. The KPD Work Group additionally established a calculated panel reactive antibody (CPRA) threshold at which candidates would only match with donors that had been pre-accepted. Based on data provided by UNOS staff, explained in more depth in the Supporting Evidence section below, the KPD Work Group determined that candidates with a CPRA of 90% or higher must use the donor pre-select tool to pre-accept or pre-refuse all donors with whom they may potentially match. The candidate will not match with any donor that is not pre-accepted.*

Transplant hospitals entering candidates in the KPDPP are encouraged to use this tool for candidates with any CPRA, but it is only mandatory for those candidates with a CPRA greater than or equal to 90%.

- *The supporting evidence for the Donor Pre-Select was previously reported extensively in the Kidney Committee's June 2013 report to the Board of Directors7:*
- *Over 90% of match offers are declined [between October 27, 2010 and May 2, 2012]. 20% of matches have not reported a refusal reason. 40% might have accepted the match, but the exchange was terminated by another pair.*
- *Of the remaining 40% of refused matches:*
    - *33% refused due to an actual or virtual positive crossmatch*
    - *7% due to "candidate involved in a pending exchange" (with another program)*
    - *60% due to various other donor or candidate reasons including: Donor unacceptable due to age, weight, size, medical history etc.*
- *When a match is declined, the remaining matches in that exchange are frequently terminated as well, increasing the overall decline rate.*

Pre-select should be required of all patients, regardless of PRA. Supporting evidence cited on page 6 (above). If a transplant center is required to pre-select/pre-decline, this will enable more matches to proceed to crossmatch and hopefully to transplant. With the ability to pre-select based on donor age, weight, size, medical history, etc, there is the potential for decreasing broken matches by 60% (per data above).

- *Page 5. The Kidney Committee also clarified the language to ensure that the requirement to "make available" donor records does not mean the donor's hospital must ship the records.*

UNOS PKE program must designate a method for the recipient center to receive donor records. As written, UNOS' PKE does not require donor records to be shipped (mailed), or scanned in a secure document to the recipient center. There should be a requirement to send the donor records to the recipient center within 48 hours.

- *Page 6: The Kidney Committee debated whether to require overnight shipping for the blood sample. It ultimately decided not to include the requirement, as there may be extenuating circumstances in which the matched donor, or the matched donor's transplant hospital, could not ship the blood sample overnight. However, the Kidney Committee stressed that overnight shipping is very important, and transplant hospitals should ship overnight when possible. Additionally, the matched candidate's transplant hospital could specify in its crossmatch instructions to the matched donor hospital that the blood sample must be shipped overnight.*

It should be required that all CM samples be shipped overnight. Receiving a sample, which has not been sent overnight, and receiving no viable cells for crossmatch, is a waste of time for both centers and the donor having to be re-drawn. This could, ultimately, hold up the entire chain.

- *Page 14: … If any of the transplant hospitals in the exchange fail to respond to the request for extension within 1 business day of receiving the request, the request will not be granted. If the extension request is submitted before the deadlines specified in Policy 13.10, the exchange will not terminate until the resolution of the extension request or until the deadline is reached, whichever comes first.*

There are many reasons for needing a crossmatch extension, but one center, who does not respond to a crossmatch extension, should not be able to break the entire chain. We recommend UNOS PKE have a method to reach out to the center to trouble-shoot before cancelling the chain, as improved communication may be key (e.g. Is it a new center? Does the PKE coordinator know he/she needed to respond to the crossmatch extension? Did the PKE coordinator even see this request?).