At-a-Glance

- **Proposal to Require Confirmatory Subtype Testing of Non-A_1 and Non-A_1B Donors**

- **Affected/Proposed Policy:** 3.1.2 (Transplant Center), 3.1.13 (Definition of Directed Donation), 3.2.4 (Match System Access), 3.5.9.1 (Essential Information for Kidney Offers), 3.6.2 (Blood Type Similarity Stratification/Points), 3.6.9.1 (Essential Information for Liver Offers), 3.7.12.1 (Essential Information for Thoracic Offers), 3.8.2.2 (Essential Information for Pancreas Offers), 5.0 (Standardized Packaging, Labeling, and Transporting of Organs, Vessels, and Tissue Typing Materials), 12.3 (Medical Evaluation of Living Donors), 12.7 (Responsibility for Transport of Living Donor Organs), 12.8 (Reporting Requirements).

- **Operations and Safety Committee**

  This proposal would require confirmatory subtype testing of blood group A and AB deceased or living donors when subtyping is used for the placement of organs, and the donor is identified to be subtype non-A_1 (e.g A_2) or non-A_1B (e.g A_2B). Blood samples for the initial and confirmatory subtype testing will be required to be taken on two separate occasions and be pre-transfusion specimens only.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  From July 2004 through October 2010, there were 470 ABO subtype compatible transplants reported to the OPTN. The proposed policy modifications are expected to enhance the safety of recipients receiving organs allocated based on ABO subtyping of a deceased or living donor.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal addresses the HHS Program Goals of patient safety and operational effectiveness. It also addresses the OPTN/UNOS Strategic Plan Goals by:

- Promoting safe, high-quality care for transplant candidates, transplant recipients, and living donors; and
- Promoting system improvements that best support critical network functions, and work to disseminate them to all members who could benefit.

The goal for the proposed policy modifications also meet provisions of the Final Rule as outlined in §121.6(a)[1].

- **Specific Requests for Comment**
  Please provide comment on the entire document or any portion that you feel requires further clarification. In particular, the Committee would like the community to focus on the following issues:

  - Do the proposed policy changes clarify and adequately define transplant center and organ procurement organization (OPO) responsibility for completing ABO subtyping confirmatory testing and verification?
  - Will the proposed policy changes adversely affect current OPO or transplant center practice?

[1] 42 CFR Part 121, see http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

Proposal to Require Confirmatory Subtype Testing of Non-A_1 and Non-A_1B Donors

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Operations and Safety Committee

Summary and Goals of the Proposal:

This proposal would require confirmatory subtype testing of blood group A and AB deceased or living donors when subtyping is used for the placement of organs, and the donor is identified to be subtype non-A_1 (e.g A_2) or non-A_1B (e.g A_2B). Blood samples for the initial and confirmatory subtype testing will be required to be taken on two separate occasions and be pre-transfusion specimens only.

Background and Significance of the Proposal:

In 2008, a kidney donated from a living donor, whose ABO subtyping completed prior to the donation was reported as non-A_1 (e.g. A_2), was transplanted into a blood type O recipient resulting in immediate graft rejection and organ failure. Repeat subtype testing of the donor indicated the actual subtype to be A_1. In response to this event, the Membership and Professional Standards Committee (MPSC) requested that the Operations and Safety Committee (OSC) examine current OPTN policies to evaluate whether they are adequate to ensure that subtyping of both deceased and living donors is accurately determined and verified.

In April 2010, after data review and discussion, the OSC requested that a group of experts in the field of ABO typing and subtyping be formed to assist the committee in its task. The ABO Subtyping Work Group was created and included representation from American Association of Blood Banks (AABB), a histocompatibility laboratory supervisor, a blood bank medical director, the OPTN/UNOS Histocompatibility Committee, representatives from OSC, and other transplant center and OPO personnel familiar with processes related to allocation of organs based on ABO subtyping. The OSC requested the work group to assist the committee with understanding the current practice of laboratories performing subtype testing and centers requesting completion of such tests. They were also asked to assist in proposing requirements that would be consistent with current laboratory and transplant community practice for ABO subtype testing.

The ABO Subtyping Work Group began its discussions by acknowledging that it is common practice in many donation service areas (DSA) and OPOs to provide subtyping of donors for transplant centers willing to accept organs for subtype compatible transplants. An ABO-subtype compatible transplant is defined as one in which blood type compatibility is contingent on both recipient ABO and donor subtype. The possibilities for these types of transplants are an ABO subtype non-A_1 (e.g. A_2) donor organ to be placed into a blood group B or O recipient or an ABO subtype non-A_1B (e.g. A_2B) donor organ to be placed into a blood group B recipient. Discussions focused on the fact that transplanting an ABO-incompatible organ could lead to immediate graft failure and therefore the accuracy of ABO subtype is

critical. The work group also discussed information received as patient safety events submitted to the OPTN and feedback provided by UNOS site surveyors suggesting that there is confusion within the transplant community about how to interpret laboratory reports of subtyping results. Experts within the group explained that there are a variety of ways in which laboratories report subtying results and there is currently no standard for reporting. This issue often requires OPO or transplant center personnel to interpret the results indicated on the subtyping report to allocate organs appropriately. The work group agreed that this is a potential source of miscommunication of results or errors in data entry. The group will develop a guidance document to address laboratory testing of ABO subtypes, interpretation of subtyping, and reporting of subtyping status in blood group A and AB organ donors that will assist members.

OPTN policy currently requires subtyping for all blood type A deceased donors, as well as living donors (if appropriate (i.e. when subtype is used for a subtype compatible transplant)). There are no current requirements that address responsibilities for ensuring subtyping of deceased and living donors is accurate and reproducible. Thus, after review of current policy and data reported to the OPTN related to ABO subtyping of deceased and living donors, the OSC proposes that blood group A and AB deceased and living donors, when subtyped and determined to be non-A_1 (negative for A_1, (e.g. A_2)) or non-A_1B (negative for A_1B (e.g. A_2B)), must have a confirmatory subtyping test completed to determine the accuracy of the initial subtyping result. These policy modifications are an effort to enhance safety for recipients of subtyped organs and to outline the responsibilities of OPOs and transplant centers requesting ABO subtyping to be performed whether on deceased or living donors.

The OSC determined that there must be consistency of ABO subtyping and blood typing requirements currently outlined in OPTN policy. Thus, samples taken for the initial and confirmatory subtype testing must be taken on two separate occasions defined as two samples sent to two labs, or two samples from separate draws sent to the same lab. To further enhance safety of recipients receiving organs that are placed based on ABO subtyping, the OSC proposes that subtype testing be completed on pre-transfusion specimens (specimens drawn before transfusion of red blood cells or red cell containing products) to decrease the chance of testing error after a donor has received transfusions. When samples drawn on two separate occasions are not pre-transfusion samples, or subtyping results cannot be verified or validated with a confirmation test, the donor's organs must be allocated based on the ABO type without subtype determination.

Collaboration:

During the preparation of this proposal, the OSC consulted the OPO and Living Donor Committees. The OPO Committee was asked to comment on whether or not ABO subtyping should be required to be entered into DonorNet® for electronic verification requiring two users to verify the correct ABO subtype, before generating a match run. Consultation with the OPO Committee outlined issues that could prevent many OPOs from being compliant with requirements to obtain initial ABO subtyping and confirmation testing to enter into DonorNet® prior to allocation of organs. Some OPOs do not have the capability to obtain subtyping results in a timely manner to allow for allocation of as many organs as could be placed from the donor. Therefore, this requirement would delay the placement of organs in some instances. The OSC agreed that while the correct subtype is critical for an accurate match run to be generated, it is more important that the subtype be accurate and reproducible. The Living Donor Committee (LDC) assisted the OSC in developing living donor policy language requiring ABO subtyping confirmation of living donors when subtype is used for a subtype compatible transplants. Both the OPO and LDC committees were asked to provide feedback on specific circumstances where the requirements

for ABO subtyping initial and confirmatory testing should be different for deceased versus living donors. All feedback was taken into consideration during the development of this proposal.

Alternatives considered:

The OSC considered other methods for achieving the goal of ABO subtype confirmation. The committee discussed requiring transplant centers to perform subtype confirmatory testing, in the case of deceased donors, after the organ had arrived at the center, but strongly agreed that it was too late in the process once the organ had arrived to the transplant center to be determining the accuracy of subtyping. If an error were identified in the donor's subtype once the organ had arrived, this could lead to reallocation of the organ and an increase in the cold ischemia time for which many centers may decline the offer. The OSC favored taking steps to ensure that subtype confirmation testing and verification is completed by the OPO (for deceased donors) or transplant center (for living donors) before a match can be generated using the subtype to allocate organs. It was also discussed that not all laboratories completing subtype testing at the request of OPOs and transplant centers are under the purview of the OPTN for which to require standardized terminology for reporting. Thus, the ABO Subtyping Work Group will develop a guidance document to address known issues related to laboratory testing for ABO subtype, interpretation, and reporting of subtyping status in blood group A and AB organ donors.

Strengths and weaknesses:

The strengths of the proposed policy modifications are the safety mechanisms built into the testing and verification processes. It is not expected that this proposal would place an additional burden on OPOs or transplant centers, as the proposed policy modifications outline what each center should do when the requirements of ABO subtype testing cannot be met. However, because the proposal does not specifically require OPOs and transplant programs to enter ABO subtype information into UNet^{SM}, the OPTN will not have complete data on the number of donors with A_2 or A_2B subtypes.

Intended and unintended consequences*:*

This proposal is expected to decrease instances of incompatible transplants that may occur as a result of subtype testing errors or misinterpretation of laboratory reports due to ambiguity. Safety of the recipient is expected to be enhanced due to the use of pre-transfusion specimens for testing, obtaining specimens on two separate occasions (decreasing the likelihood of labeling errors), confirmation subtype testing, and verification that the initial and confirmatory tests have resulted in the same result by two separate staff. There may be instances with some OPOs, whose centers accept subtyped organs for transplant, where time used to allocate organs is increased due to requirements to obtain and confirm subtype results, but the OSC believes that confirmation of subtype testing is critical to avoid rejection of an organ. The OSC will monitor patient safety situations reported to the OPTN that include issues related to increased time to allocate organs due to requirement of subtype confirmatory testing and verification, circumstances surrounding instances of non-compliance with these requirements, and the number of blood group A (all blood group A donors are required to be subtyped by current policy) and AB donors that were subtyped and entered into DonorNet® for matching versus those organs not allocated based on subtyping.

Supporting Evidence and/or Modeling:

As shown by [2]Bryan, et al, the error rates associated with subtyping exceed those for ABO determination. Using the sensitivity and specificity estimates provided in this article, the probability of the true subtype being A_1 (or A_1B) given a single subtype test indicates A_2 (A_2B) was estimated to be about 3.5%. If a confirmatory test also indicates A_2 (A_2B) the estimated error rate drops dramatically, to approximately 0.032%. Because analysis of OPTN data shows an increasing trend in the number of subtype-compatible transplants each year (to roughly 100 per year), if A2 and A2B determination was routinely based on just a single test, roughly 3-4 hyper acute graft rejection events are expected per year. Conversely, if A_2 and A_2B results are confirmed with a second, independent test, the expected number of events drops to approximately 1 event in 30 years. These results are summarized below in Table 1. Methodological and other details of this analysis can be found in the report, "Quantifying the Risks Associated with ABO Subtyping," which was presented to the Operations & Safety Committee in September 2009, Appendix A.

Table 1: Summary of Risk of Graft Rejection Due to ABO Mis-Subtyped as A2 (or A2B)

		Single ABO subtyping		Double ABO subtyping	
Test result	**Actual subtype**	**Error rate**	**Expected # events**	**Error rate**	**Expected # events**
A_2 (or A_2B)	A_1 (or A_1B)	3.5%	3-4 per year	0.032%	~ 1 in 30 years

Given a subtype test result of A_2 (or A_2B), the probability that the donor is really A_1 (A_1B) is estimated to be about 3.5%. This error rate drops to about 0.032% if the A_2 (A_2B) is confirmed with a second independent test.

Table 2, on the next page, shows the number of donors typed as A_2 and transplanted between July 2004 and October 2010. The 440 transplants with recipient having either B or O blood type are considered subtype-compatible.

Table 3, on the next page, shows the transplants occurring between July 2004 and October 2010 with donors typed as A_2B. The 30 transplants with recipient blood type B were subtype-compatible.

[2] Bryan, et al, "Implications of ABO Error Rates in Proficiency Testing for Solid Organ Transplantation," Transplantation 2006.

Table 2: ABO for Transplant Recipients whose Donors were Subtyped as A_2 By Organ Type and Donor Type
Transplants Performed between July 2004 – October 2010

		Recipient ABO				
		A	AB	B	O	Total
Organ	**Donor Type**					
KI	**Deceased**	1,293	67	95	29	1,484
	Living	56	2	11	74	143
LI	**Deceased**	651	16	1	225	893
	Living	.	.	.	3	3
HR	**Deceased**	268	14	.	2	284
LU	**Deceased**	220	11	.	.	231
KP	**Deceased**	104	10	.	.	114
PA	**Deceased**	47	1	.	.	48
IN	**Deceased**	26	.	.	.	26
HL	**Deceased**	4	1	.	.	5
Total		2,669	122	107	333	3,231

Highlighted columns represent subtype-compatible transplants.

Table 3: ABO for Transplant Recipients whose Donors were Subtyped as A_2B By Organ Type and Donor Type
Transplants Performed between July 2004 - October 2010

		Recipient ABO				
		A	AB	B	O	Total
Organ	**Donor Type**					
KI	**Deceased**	.	177	18	.	195
	Living	2	3	8	2	15
LI	**Deceased**	.	115	1	.	116
HR	**Deceased**	.	25	1	1	27
LU	**Deceased**	.	19	.	.	19
KP	**Deceased**	.	12	2	.	14
HL	**Deceased**	.	1	.	.	1
Total		2	352	30	3	387

Highlighted column represents subtype-compatible transplants.

The data in Tables 2 and 3 reveal that the vast majority of subtype-compatible transplants involve an A_2 donor. About half of the transplants are kidney, the other half liver, with a very small number involving other organ types. Of the subtype-compatible kidney transplants, most are either deceased donor transplants of organs that are subtype A_2 into blood type B recipients, or living donor transplants or organs that are subtype A_2 into blood type O recipients. Of the subtype-compatible liver transplants, most are deceased donor transplants or organs that are subtype A_2 into blood type O recipients.

Table 4, below, reveals an increasing trend in subtype-compatible transplantation since mid year 2004. The monthly rate of these transplants in 2010 (7.9) was, through October, somewhat lower than the rate of these transplants in 2009 (9.2); however, the pace for 2010 is still higher than at any time during the years 2004 - 2008.

Table 4: Trends in Subtype-Compatible Transplants
Includes Living and Deceased Donor Transplants, All Organs
Transplants Performed between July 2004 – October 2010

	Donor Subtype				
	A2		A2B		
	Recipient ABO		Recipient ABO		
	B	O	B	Total	Subtype-compatible transplants per month
Year of Transplant					
2004 (Jul-Dec)	4	16	0	20	3.3
2005	12	26	8	46	3.8
2006	23	41	4	68	5.7
2007	13	49	4	66	5.5
2008	19	58	4	81	6.8
2009	26	81	3	110	9.2
2010 (Jan-Oct)	10	62	7	79	7.9
Total	107	333	30	470	

Expected Impact on Living Donors or Living Donation:

This proposal will enhance the safety of and outcomes for recipients of ABO subtype-compatible living donor transplants.

Expected Impact on Specific Patient Populations:

This proposal will impact all recipients of deceased and living donor ABO subtype-compatible transplants. Data reported to the OPTN showed that 470 patients have been recipients of ABO subtype-compatible organs from June 2004 through October 2010.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

It is anticipated that the proposed modifications to OPTN policy requirements for ABO subtyping to include confirmation testing and verification of results will result in improved patient safety and recipient outcomes.

This proposal addresses the HHS Program Goal of patient safety and operational effectiveness. It also addresses the OPTN/UNOS Strategic Plan Goals to promote safe, high quality care for transplant recipients and living donor recipients.

The goal for the proposed policy modifications meet provisions of the Final Rule as outlined in §121.6(a)[3].

Plan for Evaluating the Proposal:

One year after the proposed changes are implemented, the OSC will request data of patient safety events reported to the OPTN and regarding policy violations identified related to requirements put in place for ABO subtyping confirmation testing and verification procedures. The committee will review these data to assess:

- ABO subtyping discrepancies that result in an inability to transplant an ABO subtype-compatible organ;
- Instances in which ABO subtype confirmation testing was not performed on donors identified as non-A1 or non-A1B and the associated circumstances;
- Transplant failures as a result of ABO subtyping discordant tests;
- Delays in allocation due to requirements for confirmation testing and verification;
- Hyper acute rejections as a result of ABO subtyping errors.

The above data will be reviewed yearly and as needed by the Committee to assess if additional policy modifications are required to improve patient safety in the area of ABO subtyping.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The proposed policy modifications will become effective 30 days after the transplant community receives notification of the OPTN/UNOS Board of Directors' approval. This proposal will not require programming in UNet[SM].

To implement the proposed policy modifications OPOs and transplant centers must:

- Develop, implement and comply with a procedure how it will collect pre-transplant specimens for subtype testing on two separate occasions;

- Develop, implement and comply with a procedure to verify donor ABO subtyping results with sources documents from both the original and verification test results and enter the data accurately into DonorNet;

[3] 42 CFR Part 121, see http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

- Maintain documentation that testing and verification of the above information has taken place and make this documentation available for audit.

Communication and Education Plan:

If approved by the Board of Directors, the transplant community will receive information regarding approved policy language and implementation date via a Policy Notice. A guidance document will be created to provide additional information about practices surrounding ABO subtyping and to assist with interpretation of subtyping results.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice [This notice informs community that policy modifications were approved by the OPTN/UNOS Board of Directors.]	Directors of Organ Procurement, Lab Directors/Supervisors, OPO Executive Directors, OPO Medical Directors, OPO Coordinators Transplant Administrators, Transplant Coordinators, Transplant Program Directors, Transplant Surgeons, Transplant Physicians, Transplant Social Workers, Transplant Data Coordinators	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday of each month	30 days after the board approves the change.
Notice to all transplant programs and OPOs explaining changes and providing an avenue for questions	All transplant programs and OPO Staff	Electronic - Included in the monthly e-newsletter sent on the 3rd Monday of each month	Within 30 days of Board approval
OPTN Evaluation Plan	OPTN transplant centers, OPO, and histocompatibility laboratories	Electronic – Available on the OPTN website under the policy management tab	Updates to the document are released quarterly

Monitoring and Evaluation:

The Department of Evaluation and Quality (DEQ) site surveyors will review and verify the following during on-site and desk reviews:

- Documentation of double verification of a donor's blood type
- If sub-typing was required, that two separate samples were sub-typed

DEQ staff will request a corrective action plan if the center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy Proposal:

3.1 Definitions

3.1.2 Transplant Center. A transplant center is a hospital that is a Member in which transplants are performed. A transplant center may also be called a transplant hospital. It is the responsibility of the transplanting surgeon at the transplant center receiving the organ offer for the surgeon's candidate to ensure medical suitability of donor organs for transplantation into the potential recipient, including—compatibility of donor and candidate by ABO blood type and subtype (when used for allocation). Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO and subtype (when used for allocation), with the recorded ABO and subtype (when used for allocation) of the intended recipient and UNOS Donor ID number. These actions must be documented and are subject to review upon audit.

3.1.13 Definition of Directed Donation – OPOs are permitted to allocate an organ(s) to a specific transplant candidate named by the person(s) who authorized the donation unless prohibited by state law. All recipients of a deceased donor organ(s) from a directed donation must be added to the waiting list prior to transplantation.

When the candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant center must document the reason why the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. The transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting the candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
  - ABO;
  - ABO subtype when used for allocation;
  - Serologies;
  - Donor HLA and candidate's unacceptable antigens;
  - Height; and
  - Weight.

3.2 Waiting List

3.2.4 Match System Access. OPOs are required to use the Match System (UNet^{SM}) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor as required by the following Policies:

- Policy 3.5.~~7~~9 (Minimum Information/Tissue for Kidney Offer),

- Policy 3.6.9 (Minimum Information for Liver Offers),
- Policy 3.7.~~9~~12 (Minimum Information for Thoracic Organ Offers),
- 3.8.2.2 (Essential Information for Pancreas Offers),

and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors.

- **ABO Typing**. To ensure the accuracy of the donor's ABO, ~~T~~the OPO shall be responsible for two separate determinations, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that ~~such separate verification~~ the initial and confirmatory tests have~~s~~ taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for utilizing ~~the~~ ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNet^{SM}.

- **ABO Subtyping**. When a blood type A (as required by policy 2.2.4.1) or AB donor is subtyped and found to be non-A_1 (e.g. A_2) or non-A_1B (e.g. A_2B), the OPO must complete a second confirmatory subtype test to determine the accuracy of the result. Blood samples for the initial and confirmatory subtype tests must be taken on two separate occasions, either 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab. Subtype testing must be performed only on pre-transfusion specimens. The two test results must indicate the same subtype before a match can be run using the subtype to allocate organs. When two pre-transfusion samples are not available, or the initial and confirmatory test results do not indicate the same subtype, the donor must be allocated based on the primary blood type, A or AB, and the subtype should not be entered into UNet^{SM}. The OPO shall maintain documentation that the initial and confirmatory tests have taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for two individuals to verify the accuracy of the initial and confirmatory subtyping test results by utilizing both ABO subtyping source documents and document that this process has taken place.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the transplant center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
    - ABO;

- ABO subtype when used for allocation;
- Serologies;
- Donor HLA and candidate's unacceptable antigens;
- Height; and
- Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

3.5.9.1 Essential Information for Kidney Offers. The Host OPO must provide the following information to the potential recipient center with each kidney offer:

(i) Donor name and Donor I.D. number, age, sex, and race;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(i) Blood type;
(ii) ABO subtype when used for allocation;
(v) HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab is encourages to report splits for all loci as shown in Appendix 3A;
(vi) Current history of abdominal injuries and operations;
(vii) Pertinent past medical or social history;
(viii) Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria;
(ix) Final urinalysis;
(x) Final BUN and creatinine;
(xi) Indications of sepsis;
(xii) Assurance that final blood and urine cultures are pending;
(xiii) Serologies as indicated in 2.2.4.1 qualified specimens preferred as noted in Policy 2.2.3.1);
(xiv) Current medication and transfusion history;
(xv) Recovery blood pressure and urine output information;
(xvi) Recovery medications;
(xvii) Type of recovery procedure (e.g., en bloc); flush solution and method (e.g., in situ); and flush storage solution;
(xviii) Description of typing material available, including, as a minimum for each kidney:
- One 7 to 10ml. clot (red topped) tube for ABO Verification, plus
- 2 ACD (yellow top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm wedge of spleen in culture medium, if available

(xix) Warm ischemia time and organ flush characteristics; and
(xx) Anatomical description, including number of blood vessels, ureters, and

approximate length of each, injuries to or abnormalities of the blood

NOTE: The amendments to Policy 3.5.9.1 (Essential Information for Kidney Offers) shall be effective June 1, 2011. (Approved at the November 8-9, 2010 Board of Directors Meeting)

3.6 Allocation of Livers

3.6.2 Blood Type Similarity Stratification/Points. For Status 1A and 1B transplant candidates, those with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who will accept a liver from a non-A_1 (negative for A_1 subtype, (e.g. A_2)) blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

3.6.9 Minimum Information for Liver Offers.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

(i) Donor name and Donor I.D. number, age, sex, race, height and weight;
(ii) ABO type;
(iii) ABO subtype when used for allocation;
(iv) Cause of brain death/diagnosis;
(v) History of treatment in hospital including current medications, vasopressors and hydration;
(vi) Current history of hypotensive episodes, urine output and oliguria;
(vii) Indications of sepsis;
(viii) Social and drug activity histories;
(ix) Vital signs including blood pressure, heart rate and temperature;
(x) Other laboratory tests within the past 12 hours including:
  (1) Total Bilirubin
  (2) ALT
  (3) INR (PT if INR not available)
  (4) Alkaline phosphatase
  (5) WBC
  (6) HH
  (7) Creatinine;
(xi) Arterial blood gas results;
(xii) Serologies as indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1).

3.7.12 Minimum Information for Thoracic Organ Offers.

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

(i) The cause of brain death;
(ii) The details of any documented cardiac arrest or hypotensive episodes;

(iii) Vital signs including blood pressure, heart rate and temperature;
(iv) Cardiopulmonary, social, and drug activity histories;
(v) Serologies as indicated in 2.2.4.1(qualified specimens preferred as noted in Policy 2.2.3.1);
(vi) Accurate height, weight, age and sex;
(v) ABO type;
(vi) ABO subtype when used for allocation;
(viii) Interpreted electrocardiogram and chest radiograph;
(ix) History of treatment in hospital including vasopressors and hydration;
(x) Arterial blood gas results and ventilator settings; and
(xi) Echocardiogram, if the donor hospital has the facilities.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

3.8.2.2 Essential Information for Pancreas Offers. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

1. Donor name and Donor I.D. number, age, sex, race and weight;
2. Date of admission for the current hospitalization;
3. Diagnosis;
4. Blood type;
5. ABO subtype when used for allocation;
6. Current history of abdominal injuries and operations including pancreatic trauma;
7. Pertinent past medical or social history including pancreatitis;
8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
9. Indications of sepsis;
10. Serologies as indicated in Policies 2.2.4.1 and (qualified specimens preferred as noted in Policy 2.2.3.1):
11. Current medication and transfusion history;
12. Blood glucose;
13. Amylase;
14. Insulin protocol;
15. Alcohol use (if known);
16. Familial history of diabetes; and
17. ~~HLAA, B, Bw4, Bw6, and DR antigens~~ HLA A, B, Bw4, Bw6, C, DR and DQB antigens. When reporting DR antigens, DRBI, and DRB3/4/5 must be reported. The lab is encourages to report splits for all loci as shown in Appendix 3A.

NOTE: The amendment to Policy 3.8.2.2 (#16) (Essential Information for Pancreas Offers) shall be effective June 1, 2011. (Approved at the November 8-9, 2010 Board of Directors Meeting)

5.0 Standardized Packaging, Labeling and Transporting of organs, vessels, and Tissue Typing Materials

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, ABO subtype when used for allocation, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:

- the standardized external label distributed by the OPTN contractor, or
- an alternate label that contains all information included on the OPTN contractor standardized label.

- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous
- donor organ must be removed**.**

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type, ABO subtype when used for allocation, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information and must be utilized.

5.4 INTERNAL LABELING REQUIREMENTS

5.4.1 Solid organ

The Host OPO is responsible for ensuring that ~~the~~ a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. ~~and~~ , donor ABO type~~,~~ and ABO subtype when used for allocation.

5.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique ID, (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO, ABO subtype when used for allocation, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID or ABO is not available, it is permissible to use a locally assigned unique ID and one other identifier for the transportation of initial screening specimens.

5.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO, ABO subtype when used for allocation, all serology results, container contents, and the UNOS Donor ID. If the donor is in a "high risk"[4] group as defined by the Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor

[4] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm

operating room. The label should clearly state "for use in organ transplantation only." If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

5.5.1 Documentation accompanying the organ

- Complete donor documentation–must be sent in the container with each transported organ. This documentation must include:
  - ABO typing source documentation;
  - ABO subtyping source documentation when subtype is used for allocation;
  - Infectious disease testing results;
  - Medical/Behavioral History form;
  - Donor Evaluation;
  - Complete record of the donor;
  - Consent form; and
  - Organ quality information as noted in Policy 2.5
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
  - a location specifically designed for documentation, or
  - between the outer and inner containers.
- Whenever a deceased donor organ is transported, the Host OPO or the Transplant Center, as applicable, must include in the donor documentation the source documentation.

5.6 Verification of Labeling and Documentation Included with Organs or Vessels

5.6.1 Verification of labeling and documentation for deceased donor organs or vessels.

When a deceased donor organ or vessel(s) is procured, the Host OPO must ensure the accuracy of the donor's ABO, and ABO subtype when used for allocation, on the container label and within the donor's documentation. Each OPO must establish and implement a procedure for verifying the accuracy of organ/vessel packaging labels by an individual other than the person initially performing the labeling and documentation requirements stated in policy 5.3, 5.4 and 5.5. The Host OPO must maintain documentation that such separate verification has taken place and make such documentation available for audit.

5.7 Verification of Information Upon Receipt of an Organ

Upon receipt of a deceased donor organ and prior to implantation, the Transplant Center must determine that it has received the correct organ for the correct transplant candidate by verifying the recorded donor and recipient ABO, ABO subtype when used for allocation, and UNOS Donor ID, as required by Policy 3.1.2. The Transplant Center must maintain documentation that this verification has taken place and make such documentation available for audit.

5.8 Materials for Tissue Typing and ABO Confirmation

5.8.1 Policy for tissue typing specimen, medium, and shipping requirements

Each OPO must have a written policy established with an OPTN member laboratory(s). The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

5.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO and subtype (when used for allocation), must be sent to the receiving OPO or transplant center with each deceased organ and tissue typing material. This tube must be labeled as described in Policy 5.4.2 with the exception that the blood type may not be indicated on the label, and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits). This person must monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, ABO subtype when used for allocation, serology, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be attached to the outer sterile barrier bag and information on the label must include all of the above information and all serology testing results. The appropriate packaging of vessels should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.
- The transplant surgeon must have around the clock access to the donor information prior to using the donor vessel(s) in a recipient other than the intended recipient.

12.3 Medical Evaluation of Living Donors

12.3.1 ABO Type Identification. The member transplant hospital must ABO type, ~~and subtype if appropriate,~~ each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.3.2 ABO Subtype Identification. The member transplant hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A_1 (negative for A_1 (e.g A_2)) or non-A_1B (negative for A_1B (e.g A_2B), must complete a confirmatory test prior to donation. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times and sent to the same or different laboratories. Samples tested must not be taken after a blood transfusion. When the initial and confirmatory subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient (e.g., in a paired exchange program or allocation of non-directed donor). If the results do not indicate the same subtype, the donor must be allocated based on the primary blood type, A or AB.

12.7 Responsibility for Transport of Living Donor Organs. The following policies address standardized packaging of living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an organ from a living donor is procured, the Transplant

Center shall be responsible for ensuring the accuracy of the donor's ABO and subtype (when used to determine transplant compatibility) on the container label and within the donor's documentation. The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in Policies 12.7.1 and 12.7.5. The Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of an organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and subtype (when used to determine transplant compatibility) and document this verification in compliance with Policy 3.1.2.

12.7.2 The Transplant Center is responsible for ensuring that the Donor I.D., Donor ABO type and subtype (when used to determine transplant compatibility), and a secure label identifying the specific contents (e.g., liver segment, right kidney) are attached to the outer bag or rigid container housing the donor organ prior to transport.

12.7.3 Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), date and time the sample was procured and the type of tissue. The Transplant Center is responsible for labeling the materials appropriately.

12.7.4 The Transplant Center is responsible for affixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

12.8.1 All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery.

12.8.1.1 The living donor transplant program must use ~~the~~ source documents from both the initial and confirmatory ABO typings~~,~~ and subtypings (when used to determine transplant compatibility), to enter the living donor's ABO data on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO and subtyping was correctly entered on the Living Donor Feedback Form with both the initial and confirmatory ABO typing and subtyping source documents by an individual other than the person initially entering the donor's ABO data. A transplant program must document that each ABO typing and subtyping entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to the OPTN Contractor, upon request.