- 3.5 ALLOCATION OF DECEASED KIDNEYS. Deceased kidneys must be allocated according to the following policies. The final decision to accept a particular organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of the candidate. This allows physicians and surgeons to exercise their medical judgment regarding the suitability of the organ being offered for a specific candidate; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia time and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If an organ is declined for a candidate, a notation of the reason for that decision must be made on the appropriate form and submitted promptly.
 - 3.5.1 Definition of Expanded Criteria Donor and Standard Donor. For purposes of Policy 3.5 (Allocation of Deceased Kidneys), expanded criteria donors are defined by an "X" in the decision matrix shown below indicating relative risk of graft failure for donors older than 10 years of age > 1.7, based upon the following factors: age, creatinine, CVA, and hypertension. Standard donors are all other donors. Unless specified as an expanded criteria donor or standard donor, the term donor(s) means all donors, expanded and standard. For purposes of distinguishing expanded criteria donors from standard donors, the most recent creatinine at the time of kidney placement shall be used.

Candidates who agree to receive expanded criteria donor kidneys shall be eligible also to receive standard donor kidneys according to the policies described below for allocating standard donor kidneys. The program shall obtain consent from candidates prior to their being listed for expanded criteria donor kidney transplantation.

Donor Condition	Donor Age Categories						
	< 10	10 – 39	40 – 49	50 - 59	≥ 60		
CVA + HTN + Creat > 1.5	,			x	x		
CVA + HTN				X	X		
CVA + Creat > 1.5				X	X		
HTN + Creat > 1.5			,	X	X		
CVA					X		
HTN				·	X		
Creatinine > 1.5					X		
None of the above					X		

X=Expanded Criteria Donor CVA=CVA was cause of death HTN=history of hypertension at any time Creat > 1.5 = creatinine > 1.5 mg/dl

- ABO "O" Kidneys into ABO "O" Recipients and ABO "B" Kidneys into ABO "B"

 Recipients. Blood type O kidneys must be transplanted only into blood type O candidates except in the case of zero antigen mismatched candidates (as defined in Policy 3.5.3.1) who have a blood type other than O. Additionally, blood type B kidneys must be transplanted only into blood type B candidates except in the case of zero antigen mismatched candidates (as defined in Policy 3.5.3.1) who have a blood type other than B. Therefore, kidneys from a blood type O donor are to be allocated only to blood type O candidates and kidneys from a blood type B donor are to be allocated only to blood type B candidates, with the exception for zero antigen mismatched candidates noted above. This policy, however, does not nullify the physician's responsibility to use appropriate medical judgment in an extreme circumstance.
- 3.5.3 Mandatory Sharing of Zero Antigen Mismatched Kidneys. The following policies apply to allocation of any deceased expanded criteria or standard donor kidney for which there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List with a zero antigen mismatch:

- 3.5.3.1 Definition. A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus. Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2. A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.
- 3.5.3.2 Computer Entry. Information regarding each and every deceased kidney donor must be entered into UNetSM prior to kidney allocation, to determine whether there is a zero antigen mismatch between the donor and any candidate on the Waiting List. Pre-procurement tissue typing is expected consistent with Policy 2.7 (Expedited Organ Procurement and Placement) in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys shall proceed pursuant to Policy 3.5.12 according to candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO shall provide a written explanation of the reasons to the OPTN contractor.
- Sharing. With the exception of deceased kidneys procured for simultaneous 3.5.3.3 kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors¹ if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List for whom there is a zero antigen mismatch with a standard donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch subject to time limitations for such organ offers set forth in Policy 3.5.3.5. With the exception of deceased kidneys procured for simultaneous kidney and non-renal organ transplantation as described in Policy 3.5.3.4, and deceased kidneys procured from Donation after Cardiac Death donors¹, if there is a pediatric candidate or a sensitized adult candidate (CPRA>20%) on the Waiting List who has agreed to receive expanded criteria donor kidneys for whom there is a zero antigen mismatch with an expanded criteria donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate with the zero antigen mismatch who has agreed to be transplanted with expanded criteria donor kidneys subject to time limitations for such organ offers set forth in Policy 3.5.3.5. If both donor kidneys are transplantable, the recipient center that was offered the kidney for a candidate with a zero antigen mismatch does not have the implicit right to choose between the two kidneys.

The final decision as to which of the two kidneys is to be shared rests with the Host OPO. In lieu of the four additional points for a candidate with a PRA of 80% or higher and a preliminary negative crossmatch (Policy 3.5.11.3) four additional points will be added to all candidates for whom there is a zero antigen mismatch with a standard donor and whose PRA is 80% or higher regardless of preliminary crossmatch results. For kidneys procured from Donation after

Cardiac Death donors, if there is any candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney(s) from that donor shall be offered to the appropriate OPTN Member for the candidate listed locally with the zero antigen mismatch, by blood group identical and then compatible; then to all other local candidates in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria; then to regional and then national pediatric or sensitized adult candidates (CPRA>20%) in point sequence according to Policy 3.5.11 (The Point System for Kidney Allocation) or 3.5.12 (The Point System for Expanded Criteria Donor Kidney Allocation) depending upon whether the donor is standard or defined by expanded criteria. When multiple zero antigen mismatches are found for a single donor, the allocation will be in the following sequence:

¹For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

- 3.5.3.3.1 First to identical blood type zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as follows:
 - i local candidates; then to
 - ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
 - iii 80% or higher PRA candidates on the regional waiting list;
 - iv 80% or higher PRA candidates on the national waiting list; then to
 - v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
 - vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
 - vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
 - viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
 - ix 21%-79% PRA candidates on the regional waiting list; then to
 - x 21%-79% PRA candidates on the national waiting list.
 - 3.5.3.3.2 Next (1) in the case of blood type O donor kidneys, to blood type B zero antigen mismatched candidates, first, in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and, then, to blood type A and AB zero antigen mismatched candidates, also in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys, as set forth in (i)-(xiv) below, and (2) in the case of blood type A, B, and AB donor kidneys, to all pediatric and sensitized adult candidates (CPRA > 20%) who are blood type compatible zero antigen mismatched candidates in descending point sequence in the case of standard donor kidneys, and by waiting time in the case of expanded criteria donor kidneys,

as set forth in (i)-(xiv) below:

- i local candidates; then to
- ii 80% or higher PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- iii 80% or higher PRA candidates on the regional waiting list; then to
- iv 80% or higher PRA candidates on the national waiting list; then to
- v less than 80% PRA candidates who are less than 18 years old on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- vi less than 80% PRA candidates who are less than 18 years old on the regional waiting list; then to
- vii less than 80% PRA candidates who are less than 18 years old on the national waiting list; then to
- viii 21%-79% PRA candidates on the list of OPOs which are owed a payback kidney as described in Policy 3.5.5; then to
- ix 21%-79% PRA candidates on the regional waiting list; then to
- x 21%-79% PRA candidates on the national waiting list.
- 3.5.3.4 <u>Kidney/Non-Renal Exception</u>. When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch. In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. This exception does not apply to kidney-islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized candidates as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).
- 3.5.3.5 Organ Offer Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNetSM or through the Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). For standard criteria donor (SCD) kidneys, offers must be made for at least 10 zero antigen mismatched potential recipients. If there are less than 10 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients. If there are less than 5 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:
 - allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1 (first locally, then regionally, and then nationally); or
 - allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

¹ For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. If the Host OPO chooses to share the zero antigen mismatch through UNetSM, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNetSM. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

- 3.5.4 Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates. An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.
 - 3.5.4.1 Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate Member for the candidate with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.
- 3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), 3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - Time Limit), 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor¹, six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

- 3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The kidney/non-renal exception shall be deferred until the OPO has reduced its payback obligation to less than six.
- 3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated six or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for kidneys allocated for a kidney-pancreas transplant pursuant to Policy 3.5.4, or a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, or liver. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than six.
- 3.5.5.2 Exception for Prior Living Organ Donors. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.
- 3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered long-term debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (i.e., incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.
- 3.5.6 <u>Geographic Sequence of Deceased Kidney Allocation</u>. In general, kidneys are to be allocated locally first, then regionally, and then nationally.
 - 3.5.6.1 <u>Local Allocation</u>. With the exception of kidneys that are 1) shared as a result of a zero antigen mismatch, 2) offered as payback as defined in Policy 3.5.5 or 3) are allocated according to a voluntary organ sharing arrangement as provided in Policy 3.4.6, all kidneys will be allocated first to local candidates as defined in Policy 3.1.7 the locale where the kidneys are procured.
 - 3.5.6.2 Regional Allocation. If a standard donor kidney is not accepted by any of the local transplant centers for local candidates, the kidney is to be allocated next via the regional list consisting of all candidates listed on the Waiting Lists of other Members within the same Region as the Member which procured the kidney. When a standard donor kidney is allocated regionally, it is to be offered

to Members for specific candidates in the region according to the point system described in Policy 3.5.11 in descending point order beginning with the candidate in the region who has been assigned the highest number of points. With all regionally-shared standard donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the candidate. Selection of alternate candidates must be according to the point system for standard kidney allocation. If a local potential recipient(s) who has agreed to receive expanded criteria donor kidneys is not identified (i.e., a match run and process for notifying the appropriate transplant program(s) initiated) within six hours post cross clamping of the donor aorta, the kidney is to be allocated next via the regional list consisting of all candidates who have agreed to receive expanded criteria donor kidneys listed on the Waiting Lists of other Members within the same Region as the Member which procured the kidney. When an expanded criteria donor kidney is allocated regionally, it is to be offered to Members for specific candidates in the region according to the point system described in Policy 3.5.12 in descending point order beginning with the candidate who has agreed to receive expanded criteria donor kidneys in the region who has been assigned the highest number of points. With all regionallyshared expanded criteria donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by the candidate. Selection of alternate candidates must be according to the point system for expanded criteria kidney allocation.

3.5.6.3 National Allocation. If a standard donor kidney is not accepted by any transplant center in the Region in which the Member which procured the kidney is located, the kidney is to be allocated to Members for specific candidates in the other Regions nationally according to the point system described in Policy 3.5.11 in descending point order beginning with the candidate who has the highest number of points. With all nationally shared standard donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that candidate. Selection of alternate candidates must be according to the point system for standard donor kidney allocation. If an expanded criteria donor kidney is not accepted by any transplant center in the Region in which the Member which procured the kidney is located, the kidney is to be allocated to Members for specific candidates who have agreed to receive expanded criteria donor kidneys in the other Regions nationally according to the point system described in Policy 3.5. 12 in descending point order beginning with the candidate who has the highest number of points. With all nationally shared expanded criteria donor kidneys, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points to seek alternate candidates who have agreed to receive expanded criteria donor kidneys within the OPO or other applicable Local Unit to receive the kidney in the event that the kidney cannot be used by that candidate. Selection of alternate candidates must be according to the point system for expanded criteria donor kidney allocation.

3.5.6.4 <u>Regions.</u> Members belong to the Region in which they are located. The Regions are as follows:

Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Region 2 - Delaware, District of Columbia, Maryland, New Jersey, 3.5 - 7

Pennsylvania, Northern Virginia, West Virginia

- Region 3 Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
- Region 4 Oklahoma, Texas
- Region 5 Arizona, California, Nevada, New Mexico, Utah
- Region 6 Alaska, Hawaii, Idaho, Montana, Oregon, Washington
- Region 7 Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
- Region 8 Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
- Region 9 New York
- Region 10 Indiana, Michigan, Ohio
- Region 11 Kentucky, North Carolina, South Carolina, Tennessee, Virginia
- 3.5.7 <u>Double Kidney Allocation.</u> Kidneys from adult donors must be offered singly unless the donor meets at least two of the following conditions and the OPO would not otherwise use the kidneys singly:
 - (i) Donor age greater than 60 years;
 - (ii) Estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission;
 - (iii) Rising serum creatinine (greater than 2.5 mg/dl) at time of retrieval;
 - (iv) History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus);
 - (v) Adverse donor kidney histology (defined as moderate to severe glomerulosclerosis (greater than 15% and less than 50%).

Kidneys offered for double kidney allocation will be allocated, first locally, then regionally, and then nationally, according to the sequence and point system described in Policies 3.5.6 and 3.5.11.

- 3.5.8 Expanded Criteria Donor Kidney Allocation. Kidneys from expanded criteria donors must be offered for candidates who have agreed to receive these organs in accordance with the geographic sequence of deceased kidney allocation set forth in Policy 3.5.6 and pursuant to the point system described in Policy 3.5.12.
- 3.5.9 Minimum Information/Tissue for Kidney Offer.
 - 6.5.9.1 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;
 - (iv) Blood type;
 - (v) HLAA, B, Bw4, Bw6, and DR antigens;
 - (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) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
 - (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
- 3.5.9.2 Desirable Information for Kidney Offers. With each kidney offer, the
 Host OPO or donor center is encouraged to provide the recipient center with the
 following biopsy information for all ECD kidneys and for all non-ECD kidneys
 at the request of the accepting surgeon. To ensure an optimal kidney biopsy, it
 is recommended that:
 - (i) the wedge technique be used;
 - (ii) the sample measures approximately 10mm (length) x 5mm (width) x 5mm (depth);
 - (iii) a minimum of 25 glomeruli are captured in the sample; and
 - (iv) a frozen section slide or the biopsy material accompanies the kidney for review.

3.5.10 [RESERVED]

- 3.5.11 The Point System for Kidney Allocation. When information about a standard donor is entered into the Match System, all candidates who have an ABO blood type that is compatible with that of the donor and who are listed as active on the Waiting List will be assigned points and priority as follows:
 - 3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNetSM; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNetSM, including whether the candidate met the following criteria.
 - measured (actual urinary collection) or calculated or creatine clearance or GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
 - initiation of chronic maintenance dialysis (defined as dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) candidate in a hospital based, independent (non-hospital based), or home setting).

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. While not required for purposes of initiating waiting time, programs shall report whether or not pediatric candidates are on dialysis, and if on dialysis, a dialysis start date. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

- 3.5.11.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative time of waiting. For example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive I point $(75/75 \times 1 = 1)$. The next person in order would receive a fraction of one point defined by the following equation: $74/75 \times 1 = X$. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local and regional lists.
- 3.5.11.2 Quality of Antigen Mismatch. Points will be assigned to a candidate based on the number of mismatches between the candidate's antigens and the donor's antigens at the DR locus. An antigen mismatch occurs when a donor antigen would be recognized by the recipient as being different from the recipient's own antigens. Quality of match points are assigned as follows:
 - 2 points if there are no DR mismatches, as defined in the table below or;
 - 1points if there is 1 DR mismatch as defined in the table below.

Mismatch Category	# HLA Locus Mismatches				
	A	В	DR · .		
0 ABDR MM	0	0	0		
O DR MM	0	1	0		
	. 0	2	0		
:	1	0	0	_	
	1	1	0		
	1	2	0		
	2	0	0		
	2	1	0		
	2	2	0	_	
1 DR MM	0	0	1		
	0	1	1	_	
	0	2	I		
	1	0	I		
	1	1	I	_	
	1	2	1	_	
	2	0	1	_	
	2	1	1		
**	2	2	1		

Antigens that are considered to be equivalent for matching purposes are currently shown in Appendix-C of UNetSM User's Manual Appendix A to Policy 3.

The amendments to Policy 3.5.11.2 (Quality of Antigen Mismatch) shall be effective following notice to the membership.

There is a pair of antigens at each HLA locus. Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus (i.e., When only one of the antigens in the pair at an HLA locus is identified, the other antigen is presumed to be identical). For example, a donor typed as A2, A-(blank) would be considered A2, A2. In the following example,

the recipient would receive 2 points for having a zero, DR mismatch (no mismatches at DR locus) because the recipient would not recognize any DR donor antigens as foreign.

Donor Phenotype	Recipient Phenotype		
A23, A- (blank)	A1, A9		
B7, B8	B7, B8		
DR, DR4	DR1, DR4		

- 3.5.11.3 Sensitized Wait List Candidates Calculated PRA (CPRA). CPRA is the percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. Sensitized Waiting List candidates with defined unacceptable HLA antigens that yield a CPRA of 80% or greater will be assigned 4 points. Each transplant center may define the criteria for unacceptable antigens that are considered as contraindications for transplantation. Unacceptable antigens that are defined by laboratory detection of HLA specific antibodies must be determined using at least one solid phase immunoassay using purified HLA molecules. It is the prerogative of the transplant center to establish criteria for additional unacceptable antigens, such as repeat transplant mismatches. The CPRA will be calculated automatically when the unacceptable antigens are listed or updated on the Waiting List. The CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial/ethnic groups in proportion to their representation in the national deceased donor population.
- 3.5.11.4 Medical Urgency. No points will be assigned to candidates based upon medical urgency for regional or national allocation of kidneys. Locally, the candidate's physician has the authority to use medical judgment in assignment of medical urgency points if there is only one renal transplant center. When there is more than one local renal transplant center, a cooperative medical decision is required prior to assignment of medical urgency points.
- 3.5.11.5 Pediatric Kidney Transplant Candidates. Kidney transplant candidates who are less than 11 years old shall be assigned four additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. Candidates who are 11 years old or older but less than 18 years old will be assigned three additional points for allocation of kidneys from donors with whom the candidate shares a zero antigen mismatch. These points shall be assigned when the candidate is registered on the Waiting List and retained until the candidate reaches 18 years of age.
 - 3.5.11.5.1 Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged less than 35 Years. Kidneys from donors aged less than 35 years that are not shared mandatorily for 0 HLA mismatching, for renal/non-renal organ allocation, or locally for prior living organ donors pursuant to Policy 3.5.11.6 (Donation Status) shall be offered first for transplant candidates who are less than 18 years of age at listing irrespective of the number of points assigned to the candidate relative to candidates 18 years old and older, with the exception of candidates assigned 4 points for PRA levels of 80% or greater under Policy 3.5.11.3 (Panel Reactive Antibody) who otherwise rank higher than all other listed candidates based upon total points assigned under policy. When multiple pediatric transplant candidates are eligible for organ offers under this policy, organs shall be allocated for these candidates in descending point sequence with the candidate having the highest number of points receiving the highest priority. For purposes of assigning allocation priority among pediatric candidates for

kidneys from donors aged less than 35 years under this Policy 3.5.11.5.1, one additional point shall be assigned for candidates who are less than 11 years old; only in the case of candidates who are zero antigen mismatched with Donation after Cardiac Death donor kidneys allocated regionally or nationally, four (rather than one) additional points shall be assigned for candidates who are less than 11 years old and three additional points shall be assigned for candidates who are 11 years old or older but less than 18 years old. The priority assigned for pediatric candidates under this policy does not supercede obligations to share kidneys as a result of a zero antigen mismatch pursuant to Policies 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) and 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).

- 3.5.11.6 Donation Status. A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting.
- 3.5.12 The Point System for Expanded Criteria Donor Kidney Allocation. When information about an expanded criteria donor is entered into the Match System, all candidates who have agreed to receive expanded criteria donor kidneys, have an ABO blood type that is compatible with that of the donor, and who are listed as active on the Waiting List will be assigned points and priority as follows:
 - 3.5.12.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney or combined kidney/pancreas transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNetSM; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNetSM, including whether the candidate met the following criteria.
 - measured (actual urinary collection) creatinine clearance level or calculated GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
 - initiation of dialysis.

"Time of waiting" for candidates listed for an isolated kidney or combined kidney/pancreas transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

- 3.5.12.1.1 Time of Waiting Points. Once the minimum criteria listed above are met and "time of waiting" begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative time of waiting. example, if there are 75 persons of O blood type waiting for kidneys, the person waiting the longest would receive 1 point $(75/75 \times 1 = 1)$. The next person in order would receive a fraction of one point defined by the following equation: $74/75 \times 1 = X$. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local and regional lists.
- 3.5.13 Choice of Right Versus Left Donor Kidney. Except in the case of donor kidney(s) offered for zero antigen mismatched candidates under Policy 3.5.3 (Sharing of Zero Antigen Mismatched Kidneys) or for kidney and non-renal organ transplantation, the recipient center offered a kidney for a candidate based upon priority on the waiting list may select which of the two kidneys it will receive, if both kidneys from the donor are transplantable.
- 3.5.14 <u>Broad and Split Antigen Specificities</u>. HLA matching of A, B, and DR locus antigens is based on the antigens which are listed in Appendix 3A. Appendix 3A will be updated annually by the Histocompatibility Committee. For matching purposes, split antigens not on this list will be indicated on the Waiting List as the parent antigens and will match only with the corresponding parent antigens. Laboratories are encouraged to assign all splits.
- 3.5.15 <u>Local Conflicts</u>. Regarding allocation of kidneys, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Kidney and Pancreas Transplantation Committee and Board of Directors.
- 3.5.16 Allocation of Deceased Kidneys with Discrepant HLA Typings. Allocation of deceased kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the donor, the kidney may be allocated in accordance with the original HLA typing, or the recipient center may reallocate the kidney locally, according to Policy 3.5.
- 3.5.17 Prospective Crossmatching. A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.