

3.2 WAITING LIST. The following policies pertain to the Waiting List.

3.2.1 Mandatory Listing of Potential Recipients. All candidates who are potential recipients of deceased organ transplants must be listed on the Waiting List.

3.2.1.1 Prohibition of Listings by Non-Members. Only Members will be permitted to have access to the Waiting List. Members may not add candidates to the Waiting List on behalf of transplant centers which are not Members.

3.2.1.2 Permissible Access to UNetSM. The purpose of this policy is to protect confidential and/or sensitive information in UNetSM. UNetSM is the web-based electronic utility used by the OPTN Contractor to conduct the business of the OPTN. UNetSM is comprised of the Match System, all computer software, applications, and security architecture utilized by the OPTN Contractor to fulfill the responsibilities of the OPTN. Institutional Members are permitted access to the Match System. Institutional Members may not allow non-members access to the Match System nor use the Match System on behalf of non members unless all of the following criteria are met:

- i) the non member is a third party assisting the Institutional Member with:
facilitating transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN; and
- ii) the member institution has in place a data use agreement (DUA) with the third party that thoroughly addresses issues of confidentiality and security. At a minimum, the DUA must include the following elements:
 - a. rights in data;
 - b. access to patient-identified data;
 - c. use of data;
 - d. data confidentiality procedures;
 - e. disposition of data upon completion of contracted task;
 - f. procedures to protect patient-identified data in the event of a breach, inadvertent or otherwise; and
 - g. remedies in the event of a violation of the data use agreement.

The member institution must maintain a copy of this DUA and provide it to the OPTN contractor upon request.

3.2.1.3 Prohibition for Non-Approved Programs. No Member shall add a candidate to the Waiting List for a transplant procedure for which Member has not received approved program status. Nor shall a Member add another Member's candidate to the Waiting List for a transplant procedure for which the other member has not received approved program status.

3.2.1.4 Prohibition for Organ Offers to Non-Members. Members shall not provide organs to non-Member Transplant Centers except to Transplant Centers in foreign countries. Exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

3.2.1.5 Renal and Renal-Pancreas Combination Candidate Listing. In order to list a potential recipient of a kidney ~~or a kidney-pancreas combination~~ transplant on the Waiting List, the potential recipient's complete HLA antigen information (at least 1 A, 1 B, and 1 DR antigen) must be included at the time of listing the potential recipient. This requirement shall not apply to potential recipients listed for combined kidney-nonrenal transplantation, with the exception of kidney-pancreas transplantation as specified in Policy 3.8.2. (inclusion of HLA Data). The entry of the complete HLA antigen information for candidates on the Waiting List shall require the use of current World Health Organization (WHO) Nomenclature. (This requirement that WHO nomenclature be used shall be implemented with the implementation of the New Data Collection Forms.)

3.2.1.6 Registration of *In Utero* Transplant Candidates. Registration of an *in utero* transplant candidate on the Waiting List is appropriate only when prenatal diagnostic tests confirm that the *in utero* candidate is viable and medically suitable to receive an organ transplant. The risk of associated complications becomes appropriately low at between 32 and 36 weeks gestation. An *in utero* transplant candidate shall be listed under a special status code on the Waiting List.

3.2.1.7 *In Utero* Waiting Time. If an *in utero* candidate is not assigned a thoracic organ transplant prior to delivery on the basis of Policy 3.2.1.6, the candidate's waiting time will recommence from the time of birth with the candidate listed under the regular status code.

3.2.1.8 Waiting Time Modification

3.2.1.8.1 Permissible Modifications Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in removing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
- An error occurred in listing, modifying, or renewing the candidate's waiting list record for a Status 1 liver, Status 1A heart, or Priority 1 pediatric lung candidate and the Transplant Program requests a modified waiting time to correct any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate needs a second organ while waiting for a heart, liver, or lung, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.
- The candidate needs a second organ while waiting for a kidney, pancreas, or intestine, routine alternative therapies are not possible, the other Transplant Programs within the OPO and the OPO itself agree to the modified waiting time, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies. If an application does not comply with the requirements of Policy 3.2.1.8, then the OPTN Contractor will neither implement the requested waiting time modifications nor forward the application for review.

3.2.1.8.2 Application To apply for a waiting time modification, a candidate's Transplant Program must submit an application to the OPTN Contractor with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.

2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 *et seq.*).
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

3.2.1.8.3 Expedited Modifications of Waiting Time Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.2.1.8.4 Modifications of Waiting Time All other applications for waiting time modifications must use the following process:

1. Upon receipt of a complete application and approval or explanation of disagreements from all applicable Transplant Programs within the local unit where the candidate is registered, the OPTN Contractor will forward the application, without person-identified data, as follows:

If the candidate requests a modification on the following organ waiting list:	Then the application will be reviewed by the:
Kidney	Kidney Waiting Time Modifications Subcommittee
Liver	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee
Thoracic	A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee
Pancreas	Pancreas Waiting Time Modifications Subcommittee
Intestine	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee

Review of Waiting List Modification Applications

2. The reviewer will determine if it is appropriate to modify the candidate's waiting time as requested in the application and notify the OPTN Contractor of the decision.

3. Upon notice, the OPTN Contractor will implement the waiting time modification.
4. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.
5. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.2.1.9 Waiting Time Transferal. For the purpose of this policy, "primary waiting time" shall mean the longest time period a candidate listed on the Waiting List has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. A candidate may transfer his/her primary waiting time from one transplant center (Initial Primary Center) to another center (New Primary Center) upon listing of the individual as a transplant candidate by the New Primary Center. After receipt of a Wait Time Transfer Form, the date the candidate first met waiting time criteria (the date from which primary waiting time will be calculated) at the New Primary Center will be modified in UNetSM by the Organ Center as the date the candidate met waiting time criteria at the Initial Primary Center. Subsequent to the receipt of this request, the candidate is to be deleted from the Waiting List of the Initial Primary Center. A notice of the primary waiting time transfer will be sent from the Organ Center to each of the centers involved.

3.2.2 Multiple Listings Permitted. Candidates may be waitlisted at multiple transplant centers. These transplant centers may be located within the same OPO service area. These transplant centers may be located within different OPO service areas.

3.2.2.1 Waiting Time Transferal for Multiple Listed Candidates. For the purpose of this policy, "primary waiting time" shall mean the longest time period a candidate listed on the Waiting List has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. A candidate may transfer his/her primary waiting time from one transplant center (Initial Primary Center) to another center (New Primary Center) upon listing of the individual as a transplant candidate by the New Primary Center. After receipt of a Wait Time Transfer Form the date the candidate met waiting time criteria (the date from which primary waiting time will be calculated) at the New Primary Center will be modified in UNetSM by the Organ Center as the date the candidate met waiting time criteria at the Initial Primary Center. The candidate will be assigned a new primary waiting time date in the Waiting List record for the Initial Primary Center which corresponds with the date on which the candidate is listed at the New Primary Center. A notice of the primary waiting time transfer will be sent from the Organ Center to each of the centers involved.

3.2.2.2 UNetSM Indication of Multiple Listing. Transplant centers will be notified through UNetSM that candidates are multiple listed, but will not be notified of the identities of other centers at which the candidates are listed.

3.2.2.3 UNetSM Notification of Transplantation or Death of Multiple Listed Candidates. Transplant centers will be notified through the UNetSM system when a multiple listed candidate has been transplanted or reported as deceased by another center so that all other centers involved can investigate and request removal of the candidate from the center's Waiting List.

3.2.2.4 Non-acceptance of Multiple Listing and/or Transferal of Primary Waiting Time. Every transplant program that does not accept multiple listed candidates and/or does not allow these candidates to transfer their primary waiting time to that center if the candidate so desires, must fully inform the candidate during the transplant evaluation process or sooner.

3.2.3 Waiting Time Transferal and Multiple Listing. Every transplant program must inform every candidate about the options of multiple listing, transferring primary waiting time, and the

option to transfer their care to a different transplant center without loss of accrued waiting time, during the evaluation process, provide the candidate with written material on these options, and maintain documentation that this requirement was fulfilled

3.2.4 Match System Access. OPOs are required to use the Match System (UNetSM) 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 3.5.9 (Minimum Information/Tissue for Kidney Offer),
- Policy 3.6.9 (Minimum Information for Liver Offers),
- Policy 3.7.12 (Minimum Information for Thoracic Organ Offers),
- Policy 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, 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 an initial and second determination tests have taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure for utilizing 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 UNetSM.
- **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-A₁ (negative for A₁) or non-A₁B (negative for A₁B), the OPO must complete a second determination subtype test to assess the accuracy of the result. Blood samples for the initial and second determination subtype tests must be two separate determinations, 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 second determination test results do not indicate the same subtype, the donor must be allocated based on the primary blood type and the subtype should not be entered into UNetSM. The OPO shall maintain documentation that the initial and second determination 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 second determination 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:

- 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.

3.2.4.1 Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased. If a kidney, ~~kidney/pancreas or kidney/islet~~ transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the recipient is again added to a Waiting List for that transplanted organ, waiting time shall begin as of the date and time the candidate is relisted. ~~If the recipient is waiting for a combined kidney/pancreas or kidney/islet transplant and receives only an isolated kidney transplant, the recipient's accrued kidney waiting time shall automatically be transferred to the isolated pancreas or islet, as applicable, Waiting List.~~

3.2.4.2 Waiting Time Reinstatement for Kidney Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor kidney, the candidate may be reinstated to the Waiting List and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as: (1) kidney graft removal within the first ninety (90) days of transplant evidenced by a report of the nephrectomy for the transplanted kidney or (2) kidney graft failure within the first ninety (90) days of transplant evidenced by documentation that the candidate is either: (a) on dialysis, or (b) has measured creatinine clearance/calculated GFR less than or equal to 20 ml/min on the date that is ninety (90) days following the candidate's kidney transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Renal Waiting Time Reinstatement Form and the documentation described above. The OPTN contractor will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.

3.2.5 Preliminary Stratification. The acceptable donor size must be specified for every potential liver recipient on the Waiting List.

3.2.6 Waiting Time for Candidates in an Inactive Status. Unless otherwise stipulated in each organ specific allocation policy, waiting time beyond 30 days shall not be accrued by candidates while they are registered on the Waiting List as being inactive.

~~**3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.~~

~~**3.2.8 Previous Kidney Donor Antigens Considered “Self” Antigens in Pancreas Match Runs.** Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate’s prior kidney donor’s antigens, which will then be considered “self” antigens in pancreas match runs. In the event a candidate’s prior kidney donor’s antigens are entered, the match system for pancreas allocation will take into account the candidate’s antigens and all of the kidney donor’s mismatched antigens that are entered into UNetSM. Mismatches that are common to a candidate’s prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.~~

~~**3.2.9 Combined Kidney-Pancreas Waiting List Criteria.** Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.~~

NOTE: The amendments to Policy 3.2 (Waiting List) shall be effective pending notice to the members and programming on UNet[®]. (Approved at the November 8-9, 2010 Board of Directors Meeting)

3.2.407 Patient Notification. Transplant Hospitals are expected to notify patients in writing: (i) within ten business days (a) of the patient’s being placed on the Waiting List including the date the patient was listed, or (b) of completion of the patient’s evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the Waiting List at this time, whichever is applicable; and (ii) within ten business days of removal from the Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. Each such written notification must reference and include the OPTN contractor’s “Patient Information Letter,” which provides the telephone number that is available to patients and others to report concerns or grievances through the OPTN. All candidates currently on the waiting list should be notified by their listing center about the patient notification hotline, or other information as directed by the Executive Committee. Transplant Hospitals are further expected to maintain documentation of these notifications and make it available to the OPTN Contractor upon request for purposes of monitoring compliance with this provision. If the Member fails voluntarily to comply with this provision, the Membership and Professional Standards Committee may recommend that the Board of Directors notify the Secretary of HHS of the situation in the case of transplant programs approved by the Secretary of HHS for reimbursement under Medicare or transplant programs in Federal hospitals, or take appropriate action in accordance with Appendix L of the OPTN Bylaws in all other cases.