OPTN | UNOS

Briefing Paper

Improving the Efficiency of Organ Placement

OPTN/UNOS Organ Procurement Organization Committee

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Improving the Efficiency of Organ Placement

Affected Policies:	*1.2 Definitions, 2.2: OPO Responsibilities, 2.11: Required Deceased Donor Information, and 5.6: Receiving and Accepting Organ Offers*
Sponsoring Committee:	*Organ Procurement Organization*
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Executive Summary

On April 30, 2007, mandatory use of DonorNet® began with the goal to facilitate and expedite organ placement using an electronic organ placement system. This system allows organ procurement organizations (OPOs) to electronically notify transplant hospitals about organ offers and provide donor information. Several recent policy proposals have sought to increase broader sharing of organs (the revised kidney allocation system (KAS), the adult heart allocation system, and enhancements to liver distribution). During discussions of these proposals, the transplant community acknowledged the need to make improvements to the organ placement system in order to place organs more efficiently.

Many factors lead to inefficiencies in the organ allocation process. Some of these, such as logistical issues, are difficult to control, while OPOs and transplant programs can control other issues, such as communication. This proposal is the first step to improve the organ placement process by proposing the following:

- Reduce the current time limits for responding to organ offers
- Establish a new time limit for the primary transplant hospital to make a final decision on organ offers
- Limit the number of organ acceptances for one candidate at any given time
- Require OPOs to manage organ acceptances in real time.

This proposal also addresses the required deceased donor information by simplifying the language and reducing redundancies and inconsistencies in Policy 2.11: Required Deceased Donor Information.

This proposal primarily supports OPTN Strategic Goal 1: Increasing the number of transplants by improving the placement of organs and potentially reducing organ discards, leading to an overall increase in the number of transplants.

What problem will this proposal address?

The purpose of this proposal is to improve the placement of organs thus minimizing or eliminating any organ discards related to inefficiencies in the current system. As the OPTN moves forward with proposals to increase the broader sharing of organs, members have expressed concerns that any inefficiencies in the current system could be exacerbated with larger geographic sharing areas. Since the implementation of the revised kidney allocation system (KAS), there has been an increase in the number of kidneys shared beyond the DSA level1. Additionally, recent heart2 and liver allocation3 proposals have proposed increased sharing over a broader geographic area.

Inefficient organ placement can also lead to decreased quality of organs, especially when attempts to place organs occur post-procurement or when late reallocation occurs after an organ acceptance has been rescinded. Organ placement can be delayed as OPOs work through the lists of provisional yes acceptances. Increased donor case time can also have a negative impact on donor families as loved ones are kept on ventilator support waiting for organs to be offered and accepted.

This proposal is the first step to improve the organ placement process by reducing the current time limits for responding to organ offers, establishing a new time limit for the primary transplant hospitals to make a final decision on organ offers, limiting the number of organ acceptances for one candidate at any given time, and requiring OPOs to manage the organ acceptances in real time.

Why should you support this proposal?

The proposed policy is a step towards a more efficient organ placement system. These changes, as well as future efforts, will improve the current system and improve a system in which broader sharing of organs is expanded. Efficient organ placement can benefit both OPOs and transplant programs by potentially shortening donor case times and getting the right organs to the right candidates at the right time in the most efficient manner. Shorter case times can also provide a benefit to donor families by not prolonging the donor management process while organ placement continues. This proposal also improves Policy 2.11: Required Deceased Donor Information by reducing redundancies and inconsistencies.

How was this proposal developed?

On April 30, 2007, mandatory use of DonorNet® began with the goal to facilitate and expedite organ placement using an electronic organ placement system. This system allows OPOs to share donor information and electronically notify transplant hospitals about organ offers. The original intent of electronic notifications was to reduce the organ placement time by obtaining organ offer refusals from transplant centers. This would allow the OPOs to focus their efforts on contacting transplant centers that are interested in the organ offer. Currently, when organ offers are sent electronically, there are two offer responses available for transplant centers: refuse and provisional yes. Transplant centers enter a provisional yes acceptance when they are interested in accepting the organ or receiving more information about the organ.

The OPTN Final Rule4 states that one of the performance goals for the allocation of organs is "distributing organs over as broad a geographic area as feasible." In addition to recent changes to kidney allocation, there have been discussions to increase the broader sharing within the other organ systems. One of the goals of the new kidney allocation system (KAS), which was implemented in December 2014, was to address the variability in access to transplantation by candidate blood type and geographic

[1] https://www.transplantpro.org/wp-content/uploads/sites/3/KAS_12month_analysis.pdf

[2] https://optn.transplant.hrsa.gov/governance/public-comment/modify-adult-heart-allocation-2016-2nd-round/

[3] https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/

[4] OPTN Final Rule

location.[5] The Thoracic Organ Transplantation Committee recently proposed allocation changes to provide the most medically urgent candidates access to donors from a broader geographic area.

During early discussions regarding the broader distribution of livers, the Liver and Intestinal Organ Transplantation Committee convened a subcommittee to examine ways to increase utilization of livers. Members felt that any inefficiencies in the current organ placement system could be exacerbated with larger geographic sharing areas. Similarly, the implementation of KAS has increased the number of kidneys shared beyond the donor service area (DSA) level. Further discussions led to the acknowledgement that the problem exists across all organ types and should be addressed simultaneously.

The OPO Committee formed a joint work group made up of representatives from the organ-specific committees, the Transplant Coordinators Committee, and the Operations and Safety Committee. The work group identified their charge to evaluate and recommend policy and system changes that will increase the efficiency of organ allocation, placement and acceptance to prevent the loss or misallocation of solid organs. They also defined inefficient organ placement as "the breakdown of the normal allocation processes that results in the delay of the donation process, deviation from the match run, or the loss of an organ for transplant."

The work group identified a list of barriers to efficient organ allocation. These include:

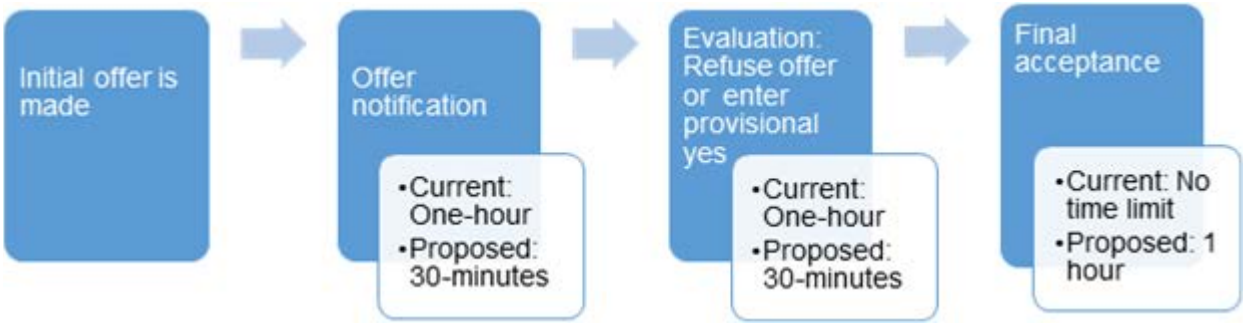
1. Time limits for responding to organ offers
2. Organ offer acceptance limits
3. DonorNet® limitations
4. Number of simultaneous offers that can be sent out at one time
5. Use of provisional yes acceptances
6. Transplant center acceptance criteria
7. Transplant center acceptance practices

This proposal will address the first two barriers while the work group continues to address the remaining barriers. This continued work could lead to additional policy changes as well as changes to DonorNet.

Time Limit for Responding to Organ Offers

The work group agreed that a first step towards improving the organ placement process is to reduce the time limits for responding to electronic offers. *Policy 5.6.B (Time Limit for Acceptance)* states that a "transplant hospital must access the deceased donor information in the match system within one hour of receiving the initial organ offer notification." Policy allows transplant hospitals an additional hour to refuse the offer or enter a provisional yes after accessing the deceased donor information. **Figure 1** shows the current and proposed organ offer time limits.

Figure 1: Current and Proposed Organ Offer Time Limits



[5] https://optn.transplant.hrsa.gov/media/2159/equity_in_access_report_201705.pdf

Most of the work group members supported shortening the response times and agreed that the current time limits for responding to electronic organ offers could be reduced from 1 hour to 30 minutes. This includes the one hour time limit for transplant centers to access the organ offer and the one hour time limit for transplant centers to enter a refusal or provisional yes response. The work group's review of data showed that responses are received within 30 minutes of initial notification (**Figure 2)** and evaluation (**Figure 3**) across all organs in 90% of cases.

Figure 2. Transplant program time from offer notification to evaluation, by organ type.

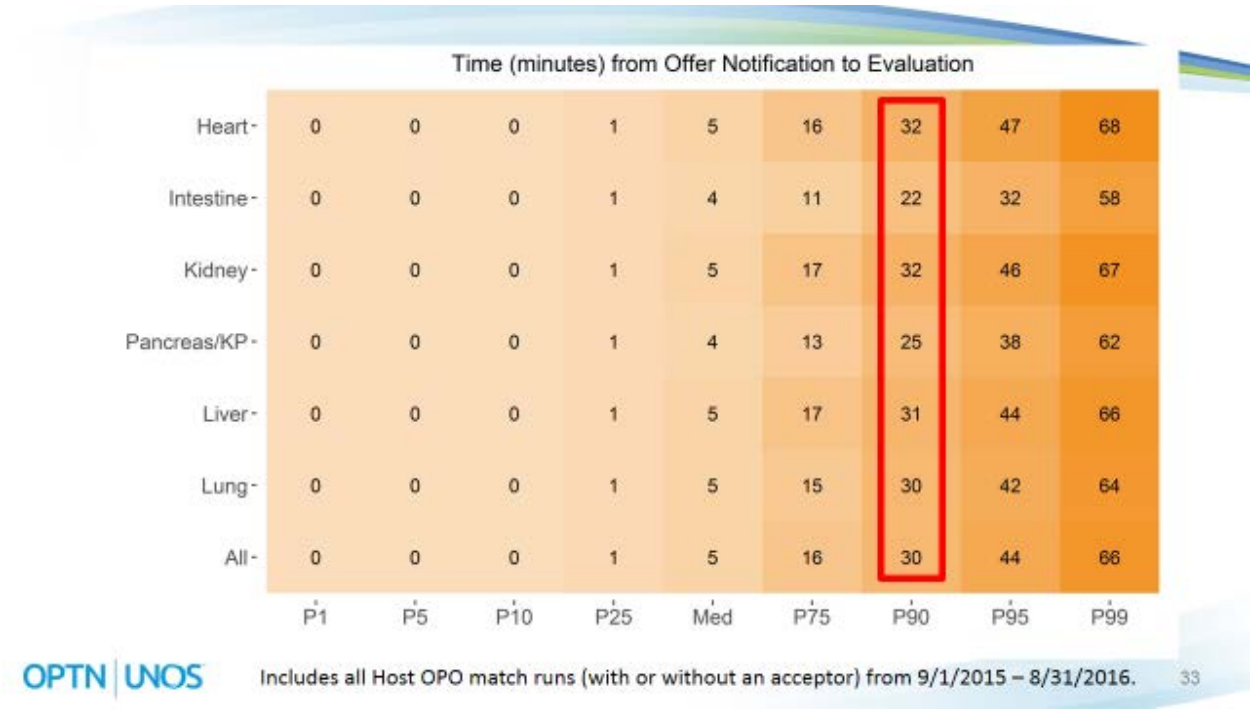
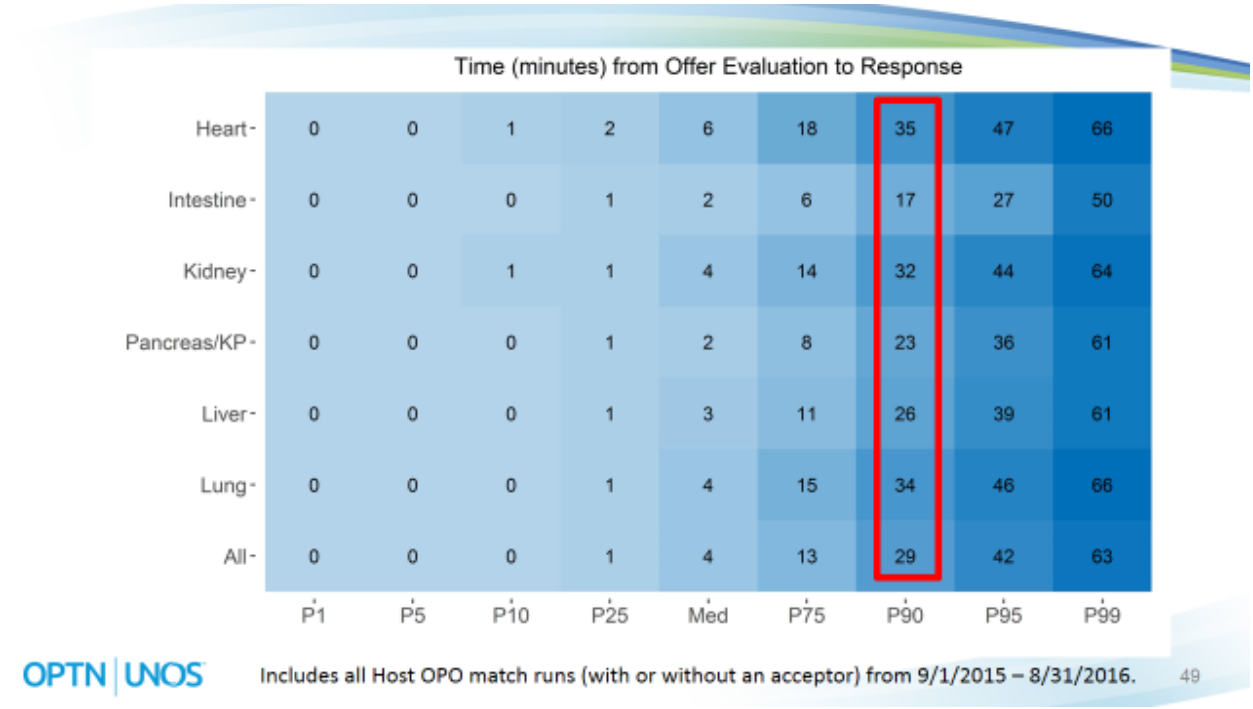


Figure 3. Transplant program time from offer evaluation to response, by organ type.



Additionally, the work group agreed that an additional time limit should be created for transplant programs to make a final decision on an offer once the OPO notifies them that their candidate is now primary. Current OPTN policy does not address how long a transplant center can take to make this final decision. This can slow down the placement process as OPOs work their way down the match run to address the provisional yes responses. The work group agreed that policy language should be added that makes it permissible for the OPO to move on to the next candidate if a final decision is not made within a certain timeframe. This final decision is either an organ offer acceptance or an organ offer refusal. The work group agreed that this should not be a mandate for OPOs to move to the next candidate on the list; there still needs to be communication between the transplant hospitals and OPOs to place organs according to the match run. If OPOs have provided all the information required by policy, transplant centers should be able to make a final decision on the organ offer. The work group members acknowledged that there can be situations where surgeons are in the operating room or more time is needed to contact the recipient. However, these are examples of operational issues that slow down the placement process and should not be allowed to hold up a final decision for extended time periods.

Because this proposal addresses provisional yes, organ offer acceptance, and organ offer refusal, the Committee is proposing policy definitions for these terms.

Limiting Offer Acceptances for the Same Organ Type at the Same Time

This proposal limits the number of offers for the same organ type that transplant hospitals can accept for a single candidate at one time. The practice of having multiple offer acceptances can lead to late declines, which causes logistical issues for OPOs resulting in forced organ reallocations. This can also undermine trust in the system by allowing transplant hospitals to hold multiple acceptances and preventing the organs from being offered to other candidates in need. The OPTN does not currently collect data on late turndowns; however, the work group acknowledged that it is a problem that could be mitigated by this proposal. OPO representatives on the work group provided anecdotal examples of waiting a significant number of hours for recovery teams to arrive for organ procurement, only to have the teams turn down the organ to accept a “better offer.” This increase in donor case time can negatively impact organ quality as well as donor families. The examples below illustrate how this problem occurs in the clinical setting:

OPO A makes a liver offer to Patient X at Center Y. Center Y accepts the organ and sends a team to recover the liver. This process takes multiple hours, during which time Patient X receives additional offers from OPO B and OPO C. When Center Y arrives on site for organ recovery, they are notified that one of the other offers is potentially a higher quality organ, and they decline the liver for Patient X. OPO A must then start the placement process over again to find a suitable candidate for the liver, but now the donor is in the operating room.

OPO A makes a liver offer to Patient X at Center Y. Operating Room (“OR”) time is set and arrangements are made to move the donor to the OR. Patient X then gets another offer, and Center Y wants to delay OR until visualization of the second liver to make sure it isn’t better than the offer from OPO A.

The work group initially discussed proposing a limit of two “provisional yes” acceptances but eventually agreed that an appropriate first step would be to limit actual organ acceptances. This will not prevent transplant programs from receiving additional offers, but will limit the number of organ offer acceptances for one candidate at any given time by organ type. The work group also agreed to apply this limit to all organ systems. Finally, the work group agreed that in order for this proposed change to work, all OPOs will need to manage the organ acceptances in real time. OPO representatives on the work group noted that if there is a benefit to managing the acceptances in real time, most OPOs would be willing to change their practices.

Changes to Policy 2: Deceased Donor Organ Procurement

Policy 2.2 OPO Responsibilities - The Committee is proposing the following modifications to the policy:

- Requiring host OPOs to ensure all the deceased donor information is provided according to *Policy 2.11: Required Deceased Donor Information*.
- Removing required deceased donor information that has been moved to Policy 2.11

Policy 2.11 Required Deceased Donor Information - While discussing the time limits for responding to organ offers, the work group agreed it was important to address the required deceased donor information. The policy outlines the OPO requirements for providing donor information to the transplant programs. The work group initially discussed creating a comprehensive list of required information to include the required fields in DonorNet®. However, it was determined that such an extensive list would be difficult to manage and keep updated. It would also reduce the flexibility for OPOs and transplant programs to share the necessary information on a case-by-case basis to best determine donor and recipient suitability. The work group identified redundancies and inconsistencies in policy. They agreed to simplify and reorganize the list of required donor information. This includes creating broad categories for certain donor information.

Below is a summary of the proposed changes:

Policy 2.11 - *Donor medical history* will include the following information currently listed in Policy 2.11.A through 2.11.E

- Date of admission for the current hospitalization
- Pertinent past medical or social history including pancreatitis
- Smoking history
- Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria
- Current medication and transfusion history
- History of medical treatment in hospital including vasopressors and hydration
- Current history of abdominal injuries and operations, including pancreatic trauma
- Cardiopulmonary, social, and drug activity histories
- Details of any documented cardiac arrest or hypotensive episodes
- Indications of sepsis
- Vital signs, including blood pressure, heart rate and temperature

Policy 2.11 - *Donor behavioral and social history* will include the following information currently listed in Policy 2.11.A through 2.11.E

- Social history and drug use
- Alcohol use
- Relevant past history and social history
- Pertinent past medical or social history including pancreatitis

Policy 2.11 – *Organ anatomy and recovery information* will include the following information currently listed in Policy 2.11.A through 2.11.E

- Recovery medications
- Recovery blood pressure and urine output information
- Type of recovery procedure, flush solution and method, and flush storage solution

  Warm ischemia time and organ flush characteristics

Policy 2.11 – *Donor evaluation information to include laboratory testing, radiologic results and injury to the organ* will contain the specific lab tests currently listed in Policy 2.11.A through 2.11.E

Policy 2.11 – *Donor management* will contain the following information currently listed in Policy 2.11.A through 2.11.E

- Vital signs, including blood pressure, heart rate and temperature

Finally, the work group discussed the requested information listed in *Policy 2.12: Requested Deceased Donor Information*. Since the information included in this section of policy is not required, the work group agreed that it could be removed from policy. The work group agreed that a guidance document should be developed that will outline best practices from both a transplant hospital and OPO perspective. For example, what type of donors might require additional tests outside of a normal donor evaluation? The work group plans to develop this guidance document in time for the public comment period beginning in January 2018.

Ongoing Work

As previously mentioned, this proposal is the first step to improving the organ placement system. The work group will continue its work to address the other barriers identified by the work group. The work group will continue to work with the UNOS Customer Advocacy department to propose changes to DonorNet® to provide better tools for OPOs and transplant centers to communicate about organ offers. The current system is not dynamic and does not provide the flexibility to adjust to the changing environment within each organ offer. These changes will be managed outside of the normal policy development process because they are not member requirements. Some of the recommendations for DonorNet® changes include:

- Notification when transplant centers when they become primary
- Notification when "critical" donor information is added or changed (organ-specific)
- Notification when certain attachments are available
- Ability to view films
- Ability to "follow a donor" – this will be an iterative process starting with operating room time to test this functionality
- Better capture information such as current medications, final infectious disease reports, vasopressor use, and blood transfusion

The work group will also revisit the issue of provisional yes acceptances and begin to address transplant hospital acceptance criteria and practices. Addressing these issues will continue the effort to improve the placement of organs.

How well does this proposal address the problem statement?

As noted earlier in this proposal document, inefficient organ allocation can lead to organ discards, impact the quality of organs, and negatively impact donor families with the increase in donor case time. With the growing possibilities of broader sharing for all organs, it is imperative to make improvements to the current system of organ placement. This proposal is the first step to improve the organ placement process by reducing the time limits for responding to organ offers, establishing a new time limit for transplant hospitals to make a final decision on organ offers, and limiting the number of organ acceptances for one candidate.

Was this proposal changed in response to public comment?

During public comment, five of the eleven regions supported the proposal in its entirety, four regions approved the proposal with amendments, and two regions did not approve the proposal. Three of the regions approving the proposal with amendments had the same recommendation to combine the

proposed 30 minute/30 minute time limit for the initial two responses to electronic organ offers to a combined 60 minutes. One region approved the proposal for all organs except kidney. Several OPTN/UNOS Committees reviewed the proposal: Liver and Intestine, MPSC, Transplant Coordinators, Transplant Administrators, Kidney and Thoracic. All were supportive of what the proposal is trying to do to improve organ placement and provided recommendations. The proposal also garnered feedback from several individuals and the following societies; their input is noted in subsequent sections below:

- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- Association of Organ Procurement Associations (AOPO)
- North American Transplant Coordinators Organization (NATCO)
- International Society of Heart and Lung Transplantation (ISHLT)

The Committee identified several similar themes identified during public comment and made several changes to the policy language to address the concerns. The themes, and the Committee's response, are detailed below.

1. Electronic Organ Offer Time Limits
2. One Hour Time
3. Organ Offer Acceptance Limit
4. Deceased Donor Information

1. Electronic Organ Offer Time Limits

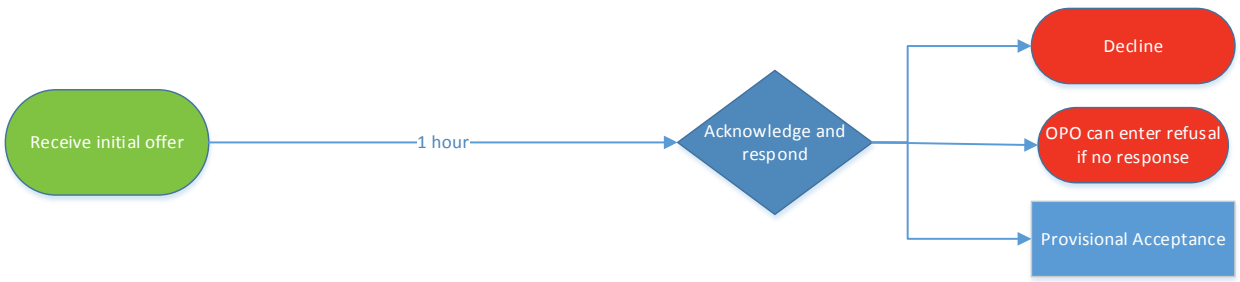
Most of the public comments were in response to the reduction in time limits for acknowledging and evaluating electronic organ offers. The Committee was proposing that the current time limit of one hour for each response be reduced to 30 minutes for each.

The comments were predominately from the transplant hospital perspective. The common concerns included:

- Not providing enough time to review information to make an informed decision
- Not enough time to consult with other members of the team
- Busy programs can have multiple offers coming in for different candidates
- Shortened time might lead to more provisional yes responses

During the development of the proposal, the Committee's review of data showed that responses were received within 30 minutes of initial notification and evaluation across all organs in 90% of cases. The Committee agreed that in order to speed up the placement of organs, the total response times should be reduced from 2 hours to 1 hour. **Figure 4** shows the proposed time limit for transplant hospitals to respond to electronic organ offers.

Figure 4. Proposed Time Limit for Responding to Electronic Organ Offers



The following commenters recommended that the two time limits be combined, allowing transplant hospitals a total response time of 60 minutes:

- Regions 4, 5, and 8
- Thoracic Organ Transplantation Committee
- Liver and Intestinal Organ Transplantation Committee
- Association of Organ Procurement Organizations

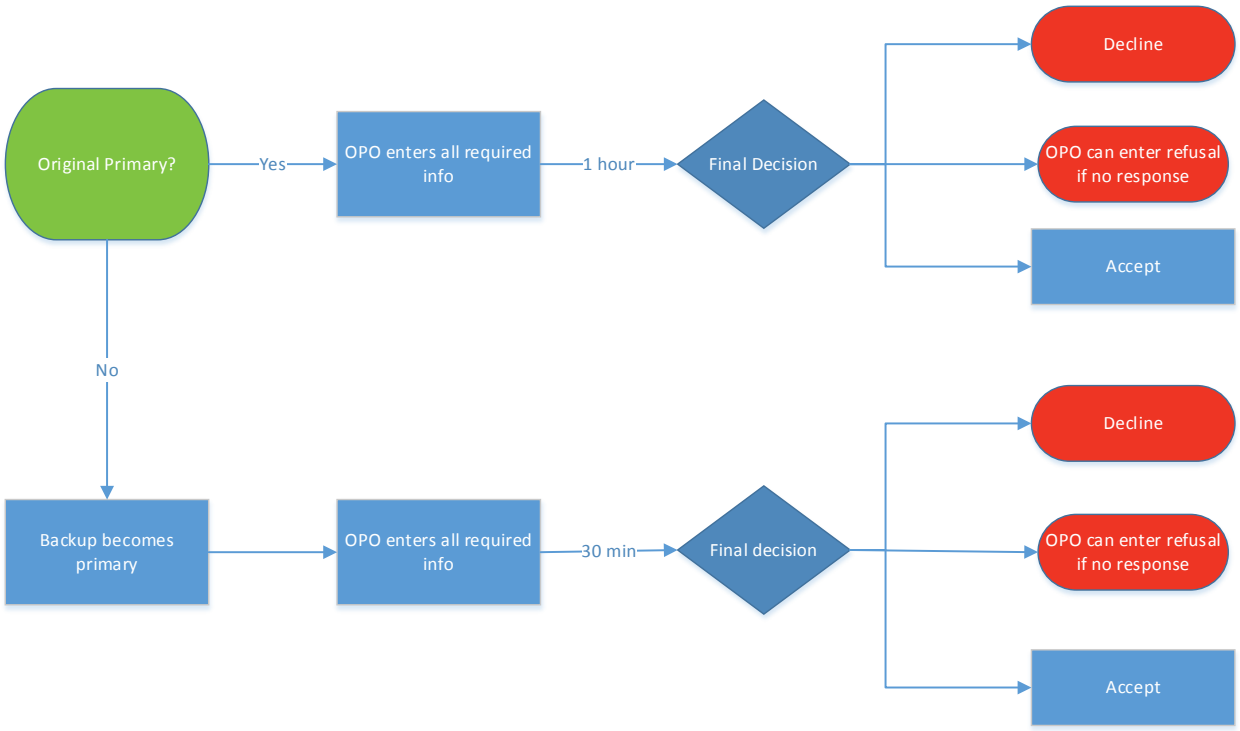
The Committee discussed the recommendation and agreed that it was a reasonable request that met the spirit of the proposal.

2. <u>One Hour Time Limit for Final Decision</u>

This proposed change received the second highest number of responses. The Committee is proposing this new time limit because there is currently no policy language that allows an OPO to move on to the next candidate on the match run if a transplant hospital does not make a timely decision once their candidate becomes the primary offer. The responses received from the OPO and transplant hospital perspectives were antithetical. From a transplant hospital perspective, the comments focused on the time limit being too short to properly evaluate the donor information. Additionally, some comments noted that kidney programs need to contact their candidates and wait for final crossmatch results. From an OPO perspective, the comments suggested that one hour was too long and would be counter to the goals of the proposal. Additionally, several OPO commenters suggested the change was in conflict with *Policy 5.4.D: Backup Organ Offers* which requires transplant hospitals to "treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ" and recommend that policy remain silent on a time limit for a final decision.

Committee leadership discussed the comments and agreed that reducing the new one hour time limit to 30 minutes was a reasonable compromise. This language was presented to the System Optimizations Work Group during a conference call on October 19, 2017 and they agreed. While reviewing the revised policy language, the OPO Committee determined that the revisions did not meet the intent of what was presented during public comment. Additionally, the Committee agreed that the policy should differentiate between the initial primary offer and all other offers with a provisional yes response. The Committee agreed to specify that the primary transplant hospital will have one hour to make a decision once all required deceased donor information has been provided by the host OPO. All other transplant hospitals with a provisional yes acceptance will have 30 minutes to make a decision once they are notified that they are now the primary offer and all required deceased donor information has been provided by the host OPO. **Figure 5** outlines the process and time limits for transplant hospitals to make a final decision once they are notified that their candidate is the primary offer.

Figure 5: Time Limit for Final Decision on Primary Offers



Another concern raised during public comment was the timing of the final crossmatch results for kidney donors. Kidney programs are hesitant to commit to an offer until they have final crossmatch results. The Committee discussed this comment and agreed that an exception should be made for final crossmatch results. Similar to the exception in the definition of organ offer acceptance that allows the organ offer acceptance to be "pending review of organ anatomy," the Committee added language stating that for "kidney offers, acceptance is also pending final crossmatch."

3. Organ Offer Acceptance Limit of Two

This proposed change did not garner many comments. The Liver and Intestinal Organ Transplantation Committee supported the proposed limit as did the American Society of Transplantation. There were several recommendations to create transparency in the system so OPOs can view how many offers are being considered for a certain candidate.

There were several recommendations to create an exception for sicker candidates, such as fulminant liver and heart/lung failure candidates. The Committee ultimately decided that an exception was not necessary because transplant hospitals can still receive offers even if they already have two organ offer acceptances. They would just need to notify one of the host OPOs and release one of the previously accepted organs.

4. Deceased Donor Information

There was general support for the OPO Committee's effort to simplify and reorganize the list of required deceased donor information. However, the Thoracic Organ Transplantation Committee and the International Society for Heart and Lung Transplantation (ISHLT) both expressed concerns about the modifications to the list of required deceased donor information. They both recommended that OPOs be required to document why a bronchoscopy cannot be performed. The Committee discussed this recommendation and added that language back into policy. They also recommended that the list of required donor information be expanded, not reduced.

The Committee discussed this recommendation and ultimately decided to leave the policy language as proposed. The work group that developed the policy proposal spent a considerable amount of time making changes to the policy to update and simplify the policy language and eliminate redundant

information. This included creating a list of general categories instead of specific lists of information. For example, the list of specific tests such as blood urea nitrogen (BUN), creatinine, and bilirubin are all captured as part of the donor medical history and donor management information and do not need to be listed separately. There is also some version of medical and social history information required across the different organs. Again, this is all captured under the general medical, behavioral, and social history category and does not need to be listed under every organ.

The Committee noted that OPOs do everything possible to maximize donors and place organs. They provide all the information required for every organ and work with transplant hospitals to provide any additional information requested. The effort to update and simplify *Policy 2.11: Required Deceased Donor Information* does not impact the commitment that OPOs have to provide transplant hospitals with the necessary information to make decisions about organ offers.

Which populations are impacted by this proposal?

This proposal will have a positive impact on candidates and donor families. Improving the efficiency of organ placement will help ensure that the right organs get to the right candidates in a timely manner. This also has the potential to benefit donor families by reducing the length of donor cases.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants*: This proposal will improve the placement of organs and decrease organ discards, leading to an overall increase in the number of transplants.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety*: There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* The reduction in time for organ offer responses can improve the efficiency of organ placement.

How will the OPTN implement this proposal?

As these policy changes affect receiving and accepting organ offers, an educational program addressing the member impact will likely be necessary.

This proposal will require programming in UNetSM.

- For reducing the time limits to respond to organ offers, the automated notifications will need to be modified:
    - Notification of organ offer – Currently, if the system is unable to reach the primary contact, it automatically attempts to notify the secondary contact by voice or text after 20 minutes. If the secondary contact cannot be reached, the system will automatically attempt to notify both the primary and secondary contacts again by voice or text. These notifications will be adjusted to accommodate the proposed changes.
- For the limit on the number of organ offer acceptances, IT is evaluating how the system will notify OPOs and transplant centers that an acceptance limit has been reached and provide them with the ability to turn down one of the previous two acceptances.

How will members implement this proposal?

This proposal will impact transplant hospitals and OPOs.

Transplant Hospitals

This proposal will require transplant hospitals to evaluate their processes for receiving organ offers. The reduction in time limits could impact those organizations that currently use third-party vendors to receive organ offers. Transplant hospitals need to be aware of the new proposed one hour limit for making a final decision once their candidate becomes the primary offer. Finally, transplant hospitals need to be aware that only two organ offer acceptances will be allowed for one candidate (for the same organ type) at the same time.

Fiscal Impact: While the policy changes require minimal time to implement, additional staff hours or hires may be needed if current staff cannot administer procurement offers within the new, shorter time limit. If current procurement volume is high, the shorter time limit for offers and acceptance my cause the need for additional staff resources. Costs may vary, depending on increased needs from in-house staff or third party/on call staff to administer procurements.

Savings will likely not exist if a two offer limit is policy. The same amount of effort or time may be needed to communicate with an OPO and clinical staff to designate the two acceptance selections.

Major variables impacting cost are existing center volume and the administration of in-house or third party services to arrange procurements.

OPOs

This proposal will require OPOs to indicate “organ placed” in DonorNet® in real time to ensure that the proposed organ offer acceptance limit meets its intended goal. OPOs should also review the changes to Policy 2.11: Required Deceased Donor Information in order to ensure timely and accurate reporting of donor information.

Fiscal Impact: The changes should be minimal cost to implement and maintain, unless there is a substantial change in procurement volume. Staff time savings may result from the offer acceptance limit and shorter timeframe. Savings may also result from fewer discards.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection. This proposal will reduce the data burden by eliminating certain required information such as echocardiograms and electrocardiograms for deceased lung donors.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

The proposed language will not change the routine allocation monitoring of OPTN members. UNOS staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to policy requirements. They will continue to investigate potential policy violations.

The following change to routine site surveys will occur based on the proposed language:

Policy 2.11.C: Required Information for Deceased Heart Donors

At OPOs, site surveyors will review a sample of deceased heart donor records for documentation of results or other evidence that an echocardiogram was performed.

Under current Policy 2.11.C, site surveyors look for results or other evidence that either a cardiology consult or an echocardiogram was performed.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The OPTN will assess the impact of these policy changes using a pre vs. post analysis at 6-months and 12-months after implementation. Analyses beyond 12-months will be performed at the request of the Committee.

The OPTN will monitor the policy change that establishes new time limits throughout the organ offer process by studying the following:

- The distribution of times from:
    - Offer notification to evaluation plus offer evaluation to response (pre-implementation) compared to offer notification to response (post-implementation)
- Usage of the bypass code for exceeding response time limits

Further, the OPTN will monitor the policy change to limit the number of concurrent offers a transplant center can accept for a single candidate in the following ways:

- At 6 months and 12 months post implementation:
    - Determine how often candidates have two concurrent final acceptances
    - Determine how often candidates have two concurrent final acceptances, is the primary potential recipient, and has a “provisional yes” entered on the match run.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

RESOLVED, that changes to Policies 2.2 (OPO Responsibilities), 2.11 (Required Deceased Donor Information, and 2.12 (Requested Deceased Donor Information), as set forth below, are hereby approved, effective March 1, 2018.

FURTHER RESOLVED, that changes to Policies 1.2 (Definitions), 5.6.B (Time Limit for Acceptance), and 5.6.C (Effect of Acceptance), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

Policy 1.2 Definitions

Organ offer acceptance
When the transplant hospital notifies the host OPO that they accept the organ offer for an intended recipient, pending review of organ anatomy. For kidney, acceptance is also pending final crossmatch.

Organ offer refusal
When the transplant hospital notifies the OPTN Contractor or the host OPO that they are declining the organ offer.

Provisional yes
When the transplant hospital notifies the OPTN Contractor or the host OPO that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ.

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the c~~C~~linical management of the deceased donor.
8. En~~As~~suring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor*

Information, is reported to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.

13~~3~~4. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt ~~to enable complete and accurate evaluation of donor suitability by transplant programs~~:

a. ABO source documentation
b. ABO subtype source documentation
c. Infectious disease results source documentation
d. Death pronouncement source documentation
e. Authorization for donation source documentation
~~f. Human leukocyte antigen (HLA) type~~
~~g. Donor evaluation and management~~
~~h. Donor medical and behavioral history~~
~~i. Organ intraoperative findings~~

14~~5~~. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.11 Required Deceased Donor Information

The host OPO must ~~obtain~~ report to the OPTN Contractor upon receipt *all* of the following information for each potential deceased donor:

1. Age
2 Diagnosis (or cause of brain death)
~~3. Sex~~
3. Donor behavioral and social history
4. Donor management information
5. Donor medical history
6. Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ
7. Ethnicity
8. Height
9. Organ anatomy and recovery information
11. Sex
12. All vital signs, including blood pressure, heart rate, and temperature
13. Weight

The potential transplant program team must have the opportunity to speak directly with responsible onsite OPO donor personnel to obtain current information about the deceased donor's physiology.

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

~~1. Date of admission for the current hospitalization~~
~~2. Donor name~~
~~3. Donor ID~~

~~4. Ethnicity~~
~~5. Relevant past medical or social history~~
~~6. Current history of abdominal injuries and operations~~
~~7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria~~
~~8. Current medication and transfusion history~~
~~9.~~1. Anatomical description, including number of blood vessels, ureters, and approximate length of each
2. Biopsy results, if performed
~~10.~~ 3. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
~~11. Indications of sepsis~~
~~12.~~ 4. Injuries to or abnormalities of blood vessels, ureters, or kidney
5. Kidney perfusion information, if performed
~~13. Assurance that final blood and urine cultures are pending~~
~~14. Final urinalysis~~
~~15. Final blood urea nitrogen (BUN) and creatinine~~
~~16. Recovery blood pressure and urine output information~~
~~17. Recovery medications~~
~~18. Type of recovery procedure, flush solution and method, and flush storage solution~~
~~19. Warm ischemia time and organ flush characteristics~~

2.11.B Required Information for Deceased Liver Donors

The host OPO must provide *all* the following additional information for all deceased donor liver offers:

~~1. Donor name~~
~~2. Donor ID~~
~~3. Ethnicity~~
~~4. Height~~
~~5. Weight~~
~~6. Vital signs, including blood pressure, heart rate and temperature~~
~~7. Social history, including drug use~~
~~8. History of treatment in hospital including current medications, vasopressors, and hydration~~
~~9. Current history of hypotensive episodes, urine output, and oliguria~~
~~10. Indications of sepsis~~
~~11. Aspartate aminotransferase (AST)~~
~~12. Bilirubin (direct)~~
1. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program
~~13.~~ 2. Other laboratory tests within ~~the past~~ 12 hours of the offer ~~including~~:
    a. Alanine aminotransferase ~~(AST)~~/asparate aminotransferase (ALT/AST)
    b. Alkaline phosphatase
    c. Total and direct bilirubin
    ~~d. Creatinine~~
    ~~e. Hemoglobin (hgb) and hemocrit (hct)~~
    ~~f~~d. International normalized ratio (INR) or Prothrombin (PT) if INR is not available~~, and~~
    e. P~~p~~artial thromboplastin time (PTT)
    ~~g. White blood cell count (WBC)~~
3. Pre-procurement biopsy results, if performed
4. Pre-procurement CT imaging results, if performed

~~14. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens in the timeframe specified by the transplant program~~

~~If a transplant program requests HLA typing for a deceased liver donor, it must communicate this request to the OPO and the OPO must provide the HLA information listed above. The transplant program must document requests for donor HLA typing, including the turnaround time specified for reporting the donor HLA typing results. The OPO must document HLA typing provided to the requesting transplant program.~~

2.11.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

~~1. Height~~
~~2. Weight~~
~~3. Vital signs, including blood pressure, heart rate, and temperature~~
~~4. History of treatment in hospital including vasopressors and hydration~~
~~5. Cardiopulmonary, social, and drug activity histories~~
~~6. Details of any documented cardiac arrest or hypotensive episodes~~
~~7.~~1.12-lead ~~interpreted~~ electrocardiogram interpretation, if available
~~8.~~2. Arterial blood gas results and ventilator settings
~~9.~~3. Cardiology consult, if performed ~~or echocardiogram, if the hospital has the facilities~~
4. Echocardiogram
~~10.~~5. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final organ acceptance

~~For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.~~

~~The heart recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite donor coordinator in order to obtain current information about the deceased donor's physiology.~~

2.11.D Required Information for Deceased Lung Donors

The host OPO must provide *all* the following additional information for all deceased lung donor offers:

~~1. Height~~
~~2. Weight~~
~~3. Vital signs, including blood pressure, heart rate, and temperature~~
~~4. History of medical treatment in hospital including vasopressors and hydration~~
~~5. Smoking history~~
~~6. Cardiopulmonary, social, and drug activity histories~~
~~7.~~1. Arterial blood gases and ventilator settings on 5 cm/H_20/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2, within 2 hours prior to the offer
~~8.~~2. Bronchoscopy results, if performed
~~9.~~3. Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer
4. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance
~~10. Details of any documented cardiac arrest or hypotensive episodes~~

~~11.~~5. Sputum gram stain, with description of sputum
~~12. Electrocardiogram~~
~~13. Echocardiogram, if the OPO has the facilities~~
~~14. HLA typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to final organ acceptance~~

If the host OPO cannot perform a bronchoscopy, it must document that it is unable to provide bronchoscopy results and the receiving transplant hospital may perform it. The lung recovery team may perform a confirmatory bronchoscopy provided unreasonable delays are avoided and deceased donor stability and the time limitations in *Policy 5.6.B: Time Limit for Review and Acceptance of Organ Offers* are maintained.

~~For lung deceased donors, if a transplant program requires donor HLA typing prior to submitting a final organ acceptance, it must communicate this request to the OPO and document the request. The OPO must provide the HLA information listed above and document that the information was provided to the transplant program.~~

~~The lung recovery team must have the opportunity to speak directly with the responsible ICU personnel or the onsite OPO donor coordinator in order to obtain current information about the deceased donor's physiology.~~

2.11.E Required Information for Deceased Pancreas Donors

The host OPO must provide *all* the following additional information for all deceased donor pancreas offers:

~~1. Donor name~~
~~2. Donor ID~~
~~3. Ethnicity~~
~~4. Weight~~
~~5. Date of admission for the current hospitalization~~
~~6. Alcohol use (if known)~~
~~7. Current history of abdominal injuries and operations including pancreatic trauma~~
~~8. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria~~
~~9. Current medication and transfusion history~~
~~10. Pertinent past medical or social history including pancreatitis~~
~~11.~~ 1. ~~Familial~~ Family history of diabetes (including Type 1 and Type 2)
2. Hemoglobin A1C, if performed
3. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
~~12.~~ 4. Insulin protocol
~~13. Indications of sepsis~~
~~14.~~ 5. Serum amylase
~~15.~~ 6. Serum lipase
~~16. HLA information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers~~

~~2.12 Requested Deceased Donor Information~~

~~2.12.A Kidney~~

~~With each kidney offer, the host OPO should provide the receiving transplant program with the following biopsy information for kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85%, and for all other kidneys at the request of the accepting surgeon:~~

1. ~~Wedge biopsy with the sample measuring approximately 10 mm (length) by 5 mm (width) and 5 mm (depth)~~
2. ~~A sample that captures a minimum of 25 glomeruli~~
3. ~~A frozen or fixed section slide, or the biopsy material, may accompany the kidney.~~

~~2.12.B Heart~~

~~With each heart offer, the host OPO should provide *all* of the following information to the receiving transplant hospital:~~

1. ~~Coronary angiography (for male donors over 40 years old or female donors over 45 years old)~~
2. ~~Central venous pressure (CVP) or Swan Ganz instrumentation~~
3. ~~Cardiology consult~~
4. ~~Cardiac enzymes, including creatinine phosphokinase (CPK) isoenzymes~~

~~A transplant hospital may request a heart catheterization of the deceased donor where the donor's medical or social history reveals at least *one* of the following past medical histories:~~

- ~~Male over 40 years old or female over 45 years old~~
- ~~Segmental wall motion abnormality on echo~~
- ~~Troponin elevation~~
- ~~History of chest pain~~
- ~~Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction~~
- ~~History of *two or more* of the following:~~
  - ~~Cocaine or amphetamine use~~
  - ~~Diabetes~~
  - ~~Hyperlipidemia~~
  - ~~Hypertension~~
  - ~~Intra-cerebral bleeding~~
  - ~~Significant smoking~~
  - ~~Strong family history of coronary artery disease~~

~~2.12.C Lung~~

~~The host OPO should provide *all* of the following information to the receiving transplant hospital:~~

1. ~~Measurement of chest circumference at the level of nipples~~
2. ~~Measurement by chest x-ray vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm~~
3. ~~Mycology sputum smear~~
4. ~~Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant hospital~~

2.13~~3~~2 Post Procurement Follow Up and Reporting

[Subsequent headings and cross-references to headings affected by the re-numbering of this policy will also be changed as necessary.]

5.6.B Time Limit for Review and Acceptance of Organ Offers

~~A transplant hospital must access deceased donor information in the match system within one hour of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused.~~

~~Transplant hospitals must either accept or refuse the organ within one hour of accessing the deceased donor information required for an organ according to *Policy 2.3: Evaluating and Screening Potential Deceased Donors*. If the transplant hospital does not respond within this time, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.~~

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

This policy does not apply to VCA transplants.

5.6.C Organ Offer Acceptance Limit

For any one candidate, the transplant hospital can only have two organ offer acceptances for each organ type. The host OPO must immediately report transplant hospital organ offer acceptances to the OPTN Contractor.

5.6.~~C~~D Effect of Acceptance

When a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ.

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