At-a-Glance

- **Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions**

- **Affected/Proposed Policy:** Policy 7.0 Data Submission Requirements (7.1 Reporting Definitions)

- **Organ Procurement Organization (OPO) Committee**

  OPOs must classify a death as one of the following: Imminent Neurologic Death ("imminent"), Eligible Death ("eligible"), or neither "eligible" nor "imminent" ("neither"). The OPOs then report the "imminent" and "eligible" deaths to the OPTN. Because OPOs interpret reporting definitions) differently (Policy 7.1), and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

  The proposed changes clarify the definitions for determining whether a death can be classified as "imminent" or "eligible." The Committee eliminated multi-system organ failure (MSOF)as an exclusionary criterion for classifying a death as "eligible" and added a list of organ- specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of "imminent" to restrict it to those deaths that would most likely be classified as "eligible" had brain death been legally declared. This could allow the combination of "eligible" and "imminent" deaths to mitigate the effect of the variation in brain death laws.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  PR/Public Education Staff

- **Number of Potential Candidates Affected**
  There is no immediate effect on candidates or the candidate pool. The Committee anticipates that with more accurate data reporting, OPOs will be able to improve their processes and better identify donor potential.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The changes support the goals of Maximum Capacity and Operational Effectiveness by trying to accurately capture the eligible and imminent deaths. These data will be used for better performance modeling.

- **Specific Requests for Comment**
  Please note that the definitions are "reporting" definitions only. They are NOT intended to be inclusive of all actual donors; therefore, they should NOT be used for screening donors or affect allocation or acceptance of organs. These criteria are not used to rule out potential organ donors and do not exclude an OPO from pursuing a donor candidate that is not classified as an Eligible Death.

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Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

OPOs must classify a death as one of the following: Imminent Neurologic Death ("imminent,"), Eligible Death ("eligible"), or neither "eligible" nor "imminent" ("neither"). The OPOs then report the "imminent" and "eligible" (I &E) deaths to the OPTN. Because OPOs interpret reporting definitions differently (Policy 7.1), and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The proposed changes clarify the definitions for determining whether a death can be classified as "imminent" or "eligible." The Committee eliminated multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as "eligible", and added a list of organ- specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of "imminent" to restrict it to those deaths that would most likely be classified as "eligible" had brain death been legally declared. This could allow the combination of "eligible" and "imminent" deaths to mitigate the effect of the variation in brain death laws.

Background and Significance of the Proposal:

The OPTN Contractor began collecting patient level data for all I & E deaths on January 1, 2008 in hopes that OPOs would have better performance modeling and would identify potential donors that might have otherwise been missed. The committee wrote I & E definitions and the Board approved them.

Please note that the imminent and eligible definitions are "reporting" definitions only. They are NOT intended to be inclusive of all actual donors; therefore, they should NOT be used for screening donors or affect allocation or acceptance of organs. These criteria are not used to rule out potential organ donors and do not exclude an OPO from pursuing a donor candidate that is not classified as an Eligible Death.

At that time, the OPO Committee sponsored two I & E training sessions to introduce the information to the community. Additionally, the AOPO Quality Council created a guidance document to help OPOs report these data accurately [Charlie Alexander, former chair of the OPO Committee provided oversight]. UNOS also created a direct e-mailbox, allowing members to ask questions and receive real-time responses (IEdeathquestions@unos.org).

In spite of these efforts, OPOs have inconsistently reported these data. Because OPOs interpret reporting definitions differently (Policy 7.1), and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The eligible death definition contains a list of exclusionary criteria. A frequently misinterpreted criterion relates to MSOF defined as "the failure of 3 or more organ systems." Some OPOs report an organ as a failed system if the organ is functioning but has some history of disease or surgery. In other words, a heart, which had undergone bypass surgery, might be listed as a failed system, when, in reality, it is a

functioning organ or system. Although this heart might not be considered an acceptable organ for transplant, it is not an organ in failure. The inconsistent way OPOs apply these definitions results in data that are not useful for interpretation or process improvement. Additionally, OPOs often pursue a single (and sometimes more) organ from these "non-eligible" donors. In 2010, there were 589 donors that resulted in at least one organ recovered for transplant that did not meet the eligible death definition. This results in inaccurate I & E data.

The Committee agreed that instead of using the number of failed systems to exclude a donor, it might be best to use the concept of "the absence of any transplantable organ" or "the presence of transplantable organ(s)." As such, a donor with any functioning organ (kidney, liver, heart or lung) that may be appropriate for transplant will be potentially identified as either an imminent or an eligible donor regardless of MSOF. After much consideration, the Committee accepted the "rule in" concept as opposed to the "rule out" model and agreed that OPOs must consider factors that "rule in" donated organs.

A data review demonstrated large inconsistencies and variations in how OPOs reported data. In order to determine why OPOs had such different reporting results, the Committee leadership contacted those OPOs that were reporting no, low or exceptionally high rates of imminent and eligible donors. They found that some OPOs were using their own definitions and not the definition found in policy, and others were interpreting the definition differently (for example, MSOF). The Committee also considered how staff turnover could affect data reporting.

Not only is there a need for OPOs to consistently apply death definitions when reporting data, the committee agreed that we need to take into account the differences in the death declaration process among hospitals throughout the US. These differences affect data reporting. For example, some states require two brain death exams while others only require one. For those requiring two, if there is no possibility of gaining authorization for donation, then there may not be an incentive to perform a second brain death exam. In this scenario, the OPO would not report this patient as eligible. Yet if the OPO was in a state that required only one brain death exam, it would likely report the patient as eligible. Even in states that only require one brain death exam, individual hospitals may require two exams which could lead to inconsistent data reporting.

Some of the fundamental concepts suggested by the committee included:

- Remove the MSOF exclusion from the definition since it is inconsistently applied. In its place should be "rule out" criteria for each individual organ system. This would result in OPOs reporting a patient as imminent or eligible if they have one organ that is transplantable, as long as that person does not have any of the other exclusionary factors. This concept is simplistic and easier to apply. This would create an inclusionary type of system because if one organ passes through the list of rule out criteria, the donor would still be included in assessment of the OPO's "conversion" rate.

- In the definitions, the current listed age range is 0 – 70 years of age. Members commented that OPOs frequently have donors over the age of 70, so the possibility of raising the age limit was discussed. After extensive discussion, it was decided that the upper range should remain the same. The lower age range for children should not be considered, however, a minimum weight should replace the age. Committee members agreed that size is a more appropriate consideration when evaluating the pediatric population and sought guidance from the Pediatric

Committee. Data was also analyzed regarding the donors over 70 to determine the effectiveness of the organs procured from that age group.

- The Subcommittee did not reach a conclusion regarding the calculation of conversion rates, but suggested a tiered approach to performance evaluation:
  - the number of eligible deaths converted to donors;
  - different ways of analyzing imminent deaths; and
  - a total conversion rate combining imminent and eligible deaths in the denominator to help to understand the OPO's potential.

- Because methods to declare death vary, it is important to understand the effect these variations can have on data reporting -- individuals with the same clinical picture may be declared dead in one state and not in another.

- In defining I & E deaths, it might encourage accurate data collection to focus on individual organs, (i.e. heart, lung, liver and kidney).

The Committee accepted these fundamental concepts and formed two work groups to identify organ-specific exclusionary criteria for each organ system and make recommended changes based on these concepts. One group focused on identifying exclusionary criteria for organs above the diaphragm and the other on organs below the diaphragm.

According to the current definition, to classify a death as an eligible death, brain death must be declared, the patient must be between 0 and 70 years of age, and have none of the exclusionary conditions (i.e. active infections, malignancy) listed in the policy. To help guide the discussion, the Committee reviewed data regarding age, weight and BMI of all donors over the last 3 years. (Attachment A) The data included the number of donors and donor yield as age or weight increases. The same was done for donor BMI. The proposed criteria were based on data that determined where less than 1% of donors fall. These parameters include 99.6% of all recovered donors on weight and BMI and would fall within the "eligible death" criteria.

After considering the data, the Committee proposed that the following changes be made to the definition:

- Add minimum weight to the definition that would
  - Exclude patients less than 5 kg or
  - Include patients that weighed 5 kg or greater

- Add Maximum Body Mass Index (BMI)
  - Exclude patients with a BMI greater than 50
  - Include patients with a BMI of 50 or less

Additionally, the Committee recommended the removal of the criteria "Multi System Organ Failure" from the list of exclusionary criteria that are included in the I & E definition. MSOF is open to interpretation and applied differently in reporting the data. In lieu of MSOF as an exclusionary criteria, the patient would be deemed eligible if they have at least one transplantable organ from the four major organs (kidney, liver, heart or lung). The Subcommittee also established a list of organ specific exclusionary criteria that would identify the organ as "not transplantable" for the purpose of this

definition. In other words, rather than ruling out a donor that has 3 or more failing organs, a donor would be "ruled in" if they have at least one transplantable organ.

The following proposed organ specific criteria were considered:

1. A patient that has at least one transplantable organ will be considered an eligible death if they meet all the criteria.

2. The kidney would be deemed suitable for transplant unless the donor has one of the following:
   - Polycystic kidney disease
   - Glomerulosclerosis ≥ 30%
   - Chronic Renal Failure
   - No urine output ≥ 24 hours
   - **No candidates on the list/exhausted the list

3. The Liver would be deemed suitable unless the donor has one of the following:
   - Cirrhosis
   - Direct Bilirubin/Total Bilirubin ≥ 15mg/dl over 24 hours with no trauma or transfusion
   - Portal hypertension
   - Macrosteotosis ≥ 60% or bridging fibrosis ≥ stage III
   - Fulminant hepatic failure
   - Terminal AST/ALT > 5000 U/L
   - **No candidates on the list/exhausted the list

4. The heart would be deemed suitable for transplant unless the donor has one of the following:
   - History of Coronary Artery Bypass Graft (CABG)
   - History of coronary stent/intervention
   - Current or past medical history of myocardial infarction (MI)
   - Severe vessel diagnosis as supported by cardiac catheterization (i.e. >50% occlusion or 2+ vessel disease)
   - Acute myocarditis and/or endocarditis
   - Heart failure due to cardiomyopathy
   - Internal defibrillator or pacemaker
   - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
   - Serial echo results showing severe global hypokenisis
   - Myxoma
   - Congenital defects (whether surgically corrected or not)
   - **No candidates on the list/exhausted the list

5. The lung would be deemed suitable for transplant unless the donor has one of the following:
   - Diagnosed COPD (emphysema)
   - Terminal P/F <250
   - Asthma (with daily Rx) in which COD due to asthma
   - Pulmonary Fibrosis
   - Previous lobectomy

- Multiple blebs documented on Computed Axial Tomography (CAT) Scan
- Pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures
- Bilateral severe pulmonary contusions as per CT
- **No candidates on the list/exhausted the list

The Committee discussed the criterion, "No candidates on the list/exhausted the list," that appears on each organ specific list. After considering multiple alternatives, the members agreed that a death should not be reported as an imminent or eligible death when an OPO evaluates and/or recovers an organ and no one will accept it. In order to define "exhausting the list, the Subcommittee recommended the following:

A death is not considered an imminent or eligible death in the following situations:

- A potential donor has no suitable organ or the OPO has exhausted the list, if either a match run has been run and all centers and patients on the list have declined the organ preoperatively.

- The donor goes to the operating room with the intent to recover organs for transplant but after seeing the organs, all surgical teams decide not to take the organs and no organs are recovered. This particular case would not be considered an imminent or eligible death.

The Committee also considered and accepted the following definition of "exhausting the list":
A death is <u>not</u> considered an imminent or eligible death if:

- The donor has no suitable organ based on the individual exclusionary criteria

- A match run has been run and all centers and patients on the list have declined the organ preoperatively.

- The donor goes to the operating room with the intent to recover organs for transplant but after seeing the organs, all surgical teams decide not to take the organs and no organs are recovered. This particular case would not be considered an imminent or eligible death.

Based on these screening criteria, if the donor has at least one organ that is transplantable, the death is classified as an imminent or eligible death, as long as it meets all of the other criteria.

Collaboration:

The Committee sought input from each of the organ specific committees and the Pediatric Transplantation Committee.

Alternatives considered:

- The Committee considered raising the age of the eligible donor but opted not to do so after reviewing the data.

- The Committee considered whether clearly defining MSOF would sufficiently encourage better data reporting. However, as they investigated the issue, they realized that the MSOF definition

did not fully describe a potential donor's condition. As such, they eliminated MSOF as an exclusionary criterion and added much more detailed organ-specific information.

- The Committee considered using the number of failed systems to exclude a donor (MSOF), but opted to use the concept of "the absence of any transplantable organ" or "the presence of transplantable organ(s)." As such, a donor with any functioning organ that may be appropriate for transplant will be potentially identified as either an imminent or an eligible donor regardless of MSOF.

- After much consideration, the Committee accepted the "rule in" concept as opposed to the "rule out" model and agreed that OPOs must consider factors that "rule in" donated organs. As such, it developed a list of exclusionary conditions that was much more definitive than "organ system failure."

- The Committee considered multiple criteria that were ultimately not included in the list. Some of the criteria that were considered included renal artery stenosis, Glomerular Filtration Rate < 80, hemophilia, and Troponin > 10. The Committee spent considerable time defining "exhausting the list" and considered many factors when doing so.

- Members also considered when a potential donor from whom no organs can be placed should not be considered an imminent or eligible death. There are situations when a potential donor meets the requirements for the eligible definition, is consented and managed as a donor, but cannot proceed to organ recovery. This situation could be caused by
  - no one willing to accept the organs,
  - if the donor is taken to the OR but organs are declined, or
  - if organs are recovered but not able to be transplanted.

- A donor who has no organs placed for transplant once organs are recovered, will not be considered an eligible death, with the caveat that failure to transplant the organ is not due to human logistics (i.e. airline loses organ, no vessels included, labeling problems). Logistical variables are not medical variables and are within the OPO's control.

- The Committee originally agreed to a minimum weight of 5 kg; however, the Pediatric Transplantation Committee considered a minimum weight of 3 kg be used. After discussion, the Pediatric Committee concluded that 5 kg should be used.

Strengths and weaknesses:

- *Strength*

The proposal more clearly defines the imminent & eligible death definitions for reporting data. It will provide a better guideline for how to report a death as imminent or eligible for more consistent data reporting and provide valuable data for process improvement and donor potential.

- *Weakness*

These changes will require education/training for individuals who are responsible for reporting these data. Also, individual data recording systems may need to be modified which may incur a cost to the member.

Description of intended and unintended consequences:

Intended consequences include improved accuracy and consistency in data reporting that will be beneficial for process improvement and identification of donor potential.

Unintended consequences include:

- The possibility that OPOs will consider these as "absolute donor rule out" definitions rather than just "reporting" definitions. These definitions are not intended to say an OPO cannot recover organs from this donor.

- The comparison of "conversion" rates pre- and post- policy modification will be affected as it would be expected that improved accuracy of eligible death data reporting will result in some OPOs reporting more eligible deaths. This will affect conversion rate calculations. While this is noteworthy, it is not considered a negative as the true value of these data is in benchmarking OPO vs. OPO or OPO vs. national mean for like time periods. As all data submitted post implementation would be impacted, the effectiveness of benchmarking should be improved by having data that are more consistent.

Supporting Evidence and/or Modeling:

To help guide the discussion, the Committee reviewed data regarding age, weight and Body Mass Index (BMI) of all donors over the last 3 years. (Attachment A) The data included the number of donors and donor yield as age or weight increases. The same type of data for donor BMI was reviewed. The proposed criteria were based on data that determined where less than 1% of donors fall. Under the proposed definition, 99.6% of all recovered donors would fall within the "eligible death" criteria on weight and BMI.

The committee reviewed data to help identify organ specific exclusionary criteria such as bilirubin, liver biopsy with % micro vesicular fat, SGOT/AST, and % glomerulosclerosis. Deceased Donor Registration data of actual donors from 2008 were analyzed to guide the Committee in setting the thresholds for the criteria listed above.

To help guide the discussion of which organs are "transplantable," the committee reviewed data that analyzed the match run data for kidney, liver, heart, and lung to assess when transplanted organs are placed (offers, centers).

The goal was to define "exhausting the list." Members considered the organ specific data regarding the number of offers made for an organ to be accepted. The Committee considered identifying thresholds for the number of centers contacted or the number of patients offered an organ that might replace "exhausting the list." While these data generated much discussion, it was decided that there were so many local and regional differences in the number of transplant programs and the size of the respective waiting lists that there was no one threshold that would be appropriate for all areas.

Expected Impact on Living Donors or Living Donation:

"Not applicable."

Expected Impact on Specific Patient Populations:

There is no known direct impact on transplant candidates or recipients. Accurate data collection could result in identifying potential donors that were not previously identified. This would result in an increase in the number of organs for transplant, and together with process improvement would result in better quality of organs for transplant.

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

The proposed changes meet the HHS Program Goals of Maximum Capacity and Operational Effectiveness. These changes have a potential to increase the donor pool resulting in an increased number of organs available for transplant. Increasing the accuracy of data reporting is a process and system improvement that supports critical network functions of data collection.

Plan for Evaluating the Proposal:

I & E data will be analyzed periodically by the OPO Committee and staff to determine if there is more consistency in data reporting.

The OPO Committee will review the I & E data every six months following implementation of the policy changes.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

Implementation of these changes will occur 30 days following Board approval. Members involved in data reporting should review the policy changes and make any modifications to their own protocols or policies that relate to I & E data reporting. Any individual responsible for I & E death data reporting should attend one of the education sessions that will be offered by UNOS.

This proposal will require programming in UNET^{SM}. There will be a minor change in UNet^{SM} to the Online Help Documentation; however, no changes will be required to any of the data fields.

Communication and Education Plan:

Because we are modifying existing definitions as well as asking members to think about applying the definitions in a new way, we need to sufficiently educate OPOs about the impact this will have on their day-to-day activities. We also need to fully communicate the changes so we can ensure all OPOs apply the new definitions consistently.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Standard policy notice	OPOs	e-newsletter	30 days after board meeting
Article in UNOS Update	OPOs & transplant centers	Print magazine	Earliest issue post board approval.
Short articles in the member archive	Same	e-newsletter	Every few months after board approval & as a heads up to any upcoming training.
Presentation or breakout by UNOS staff person at AOPO annual conference	OPOs	Live presentation	June 2012

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
Webinar to explain new definitions and how to consistently apply them.	OPOs	Live Meeting	TBD
System notice	OPOs	email	

Monitoring and Evaluation:

UNOS Department of Evaluation and Quality (DEQ) staff will review death referral information reported to the OPTN during OPO onsite reviews. DEQ staff will verify that OPOs are using the definitions in policy to report death referral information to the OPTN.

Policy or Bylaw Proposal:

7.0 DATA SUBMISSION REQUIREMENTS

7.1 REPORTING DEFINITIONS

7.1.1 – 7.1.5 [No Changes]

~~**7.1.6** Imminent Neurological Death is defined as a patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three~~

~~brain stem reflexes but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral.~~

~~Brain Stem Reflexes:~~

- ~~Pupillary reaction~~
- ~~Response to iced caloric~~
- ~~Gag Reflex~~
- ~~Cough Reflex~~
- ~~Corneal Reflex~~
- ~~Doll's eyes reflex~~
- ~~Response to painful stimuli~~
- ~~Spontaneous breathing~~

7.1.~~7~~6 Eligible Death Definition. Although it is recognized that this definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient with the following characteristics:

- 70 years old or younger;
- ~~Who ultimately~~ Is legally declared ~~brain~~ dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law; ~~according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice,~~
- Body Weight 5 kg or greater;
- Body Mass Index (BMI) of 50 kg/m^2 or less;
- Has at least one kidney, liver, heart or lung that is "deemed suitable for transplant" as defined below:
    - The kidney would be initially deemed suitable for transplant unless the donor has one of the following:
        - Polycystic kidney disease
        - Glomerulosclerosis ≥ 30% by kidney biopsy
        - Chronic Renal Failure
        - No urine output ≥ 24 hours
    - The liver would be initially deemed suitable for transplant unless the donor has one of the following:
        - Cirrhosis
        - Direct Bilirubin/Total Bilirubin ≥ 15mg/dl over 24 hours with no trauma or transfusion
        - Portal hypertension
        - Macrosteatosis ≥ 60% or bridging fibrosis ≥ stage III
        - Fulminant hepatic failure
        - Terminal AST/ALT > 5000 U/L

- The heart would be initially deemed suitable for transplant unless the donor has one of the following:
  - History of Coronary Artery Bypass Graft (CABG)
  - History of coronary stent/intervention
  - Current or past medical history of myocardial infarction (MI)
  - Severe vessel diagnosis as supported by cardiac catheterization (i.e. >50% occlusion or 2+ vessel disease)
  - Acute myocarditis and/or endocarditis
  - Heart failure due to cardiomyopathy
  - Internal defibrillator or pacemaker
  - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
  - Serial echo results showing severe global hypokinesis
  - Myxoma
  - Congenital defects (whether surgically corrected or not)
- The lung would be initially deemed suitable for transplant unless the donor has one of the following:
  - Diagnosed COPD (eg; emphysema)
  - Terminal PaO_2/FiO_2 <250 mmHg
  - Asthma (with daily Rx) in which the cause of death is due to asthma
  - Pulmonary Fibrosis
  - Previous lobectomy
  - Multiple blebs documented on Computed Axial Tomography (CAT) Scan
  - Pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures
  - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an Eligible Death UNLESS:

- The donor has no suitable organ for transplant (as defined above), or;
- ~~have exhausted the list, or;~~
- a match run has been run and all centers and patients on the list have declined the organ preoperatively, or;
- the donor goes to the operating room with the intent to recover organs for transplant but upon visualization no organ is determined suitable for transplantation.
- OR if the donor ~~who~~ exhibits ~~none~~ any one of the following:
  - ~~o~~ Active infections ~~(~~with a specific diagnoses;~~) [Exclusions to the Definition of Eligible]~~
  - Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis, ~~See "sepsis" below under "General"~~
  - Viral: HIV infection by serologic or molecular detection, Rabies, Reactive Hepatitis B Surface Antigen, Retroviral infections including HTLV I/II, Viral Encephalitis or Meningitis, Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, Acute Epstein Barr Virus (mononucleosis), West Nile Virus infection, SARS

- Fungal: Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides, Active candidemia or invasive yeast infection
- Parasites: Active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.)
- Prion: Creutzfeldt-Jacob Disease
- General [Exclusions to the Definition of Eligible]: Aplastic Anemia, Agranulocytosis
- ~~Extreme Immaturity (<500 grams or gestational age of <32 weeks)~~
- Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
- Previous malignant neoplasms with current evident metastatic disease
- A history of melanoma
- Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma
- ~~Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation~~
- Active Fungal, Parasitic, Viral, or Bacterial Meningitis or Encephalitis

7.1.6~~**7**~~**7** Imminent Neurological Death. Imminent Neurological Death is defined as a death of a patient:

- who meets the eligible death definition with the exception that ~~but~~ the patient has not been declared legally dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law, and
- who has a severe neurological injury ~~and~~ requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no spontaneous breathing and has an absence of at least ~~three~~ two additional brain stem reflexes, is considered an imminent neurological death. ~~but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral.~~

  Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- ~~Spontaneous breathing~~

7.2 – 7.9 [No Changes]