GIFT of LIFE DONOR PROGRAM
A Legacy of HEROES. A Future of HOPE.

July 29, 2025

Thomas J. Engels, Administrator

Health Resources and Services Administration

(Submitted via www.reginfo.gov/public/do/PRAMain.)

Donor Referrals:
800-KIDNEY-1
(800-543-6391)

Public Information:
800-DONORS-1
(800-366-6771)

www.donors1.org

Administrative Offices:

401 North 3rd Street
Philadelphia, PA 19123

tel 215-557-8090
fax 215-557-9359

Re: Public Comment Request: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New

Dear Mr. Engels:

On behalf of the patients, families, and communities we serve, Gift of Life Donor Program (GLDP) thanks you for the opportunity to again provide feedback on the Health Resources and Services Administration ("HRSA" or "Agency") Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network (OPTN**).** GLDP strongly supports HRSA's commitment and efforts to update and improve data collection so the nation's organ donation and transplantation system can continue to improve and meet the needs of all individuals awaiting a life-saving transplant. We thank you in advance for your consideration of our views and recommendations.

Executive Summary

We share the Agency's goal of ensuring that the government collects standardized data to help drive organ procurement organization (OPO) performance. *As such, it is with that common objective in mind that we respectfully urge HRSA to modify the Ventilated Patient Form prior to its implementation.* We maintain serious concerns that if the Agency does not make specific modifications to the form prior to implementation its use will be costly, both in terms of process improvement and stakeholder resources.

We appreciate and support the Administration's focused commitment to modernization, efficiency, and outcomes, and the engagement with the public on this important matter. As such, we are hopeful that in this iteration of the review process stakeholder input will be given full consideration and decisions regarding the final composition of the form will be explained in full to the stakeholder community. As a long-standing national leader in organ procurement, we are eager to share our organizational experience with respect to the data collection process and would welcome an opportunity to partner with HRSA in advancing data collection to support the oversight, advancement, and timely assessment of OPO performance.

About Gift of Life Donor Program

GLDP is privileged to serve as the designated OPO for the Eastern half of Pennsylvania, Southern New Jersey, and the State of Delaware for over 50 years. GLDP is the one of the nation's largest OPOs and has long been a national leader. Our unparalleled success in helping save lives is only possible through GLDP's decades-long commitment to excellence and continual process improvement, fiscal responsibility, and partnership with our healthcare community. The GLDP service area covers 121 acute care hospitals and 12 local transplant centers, with a population base of more than 11 million people. Over GLDP's history, we have coordinated more than 41,000 organs for transplant and our donation service area has contributed more organs for transplant than any other region of the country since the inception of the national system. With respect to our performance, we consistently are a Tier 1 OPO based on the metrics used by the Centers for Medicare and Medicaid Services.

Overall Feedback Regarding Process Data for OPTN

We understand HRSA proposes the use of three new data forms with the purpose of improving the OPTN organ matching and allocation process and OPTN member compliance with OPTN requirements. Two of the forms relate to transplant candidate patient registration, referral, and evaluation at transplant centers. The third form relates to data collection from the point of referral of a patient to an OPO for potential deceased organ donation (the "Ventilated Patient Form") with the goal of providing a more objective source of data on OPO practices and also to support monitoring OPO performance.

All three forms were the subject of an OPTN work group stakeholder review and assessment process in 2024 which included HRSA and then were subject to the comment period included in the Information Collection Request (ICR) to the Office of Management and Budget (OMB) in November 2024, and the current comment period. Of note, consideration was given to the feedback, and numerous changes were accepted by HRSA into the two transplant related forms *before* they were published for comment in November of 2024. **GLDP supports the implementation of those two transplant related forms as published.**

We respectfully wish to raise our concerns about both the process and content associated with the Ventilated Patient Form. While that form went through the same OPTN work group process as the two transplant center forms, when the Ventilated Patient Form was published in November 2024, and again in July 2025 HRSA did not incorporate any substantive changes based on the submitted stakeholder feedback. To date, the Agency has provided no explanation for its rejection of stakeholder input and recommendations with regard to this form. GLDP submitted comments in response to the November 2024 publication, and a copy of our submission is attached here for your reference and consideration.

We recognize that the Department of Health and Human Services and HRSA are now under new leadership and we appreciate the work being done to review previous efforts and chart a new path forward. As such, we are grateful for the Agency providing this opportunity to again submit our feedback on this important issue. We thank you in advance for ensuring that this process is governed in a transparent manner and ensures that expert input is considered and incorporated so that data collection results in the desired outcome.

Feedback on Ventilated Patient Form

GLDP again wishes to highlight its serious concerns with the proposed Ventilated Patient Form and the ability of that form to serve the goal of providing objective data to improve performance. HRSA's view of the importance of this form to its on-going oversight and timely assessment of OPOs and performance improvement was reiterated by Dr. Raymond Lynch, Organ Transplantation Branch Chief, Division of Transplant, HRSA during his testimony before the House of Representatives Energy & Commerce Subcommittee on Oversight & Investigations Hearing "Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System" on July 22, 2025.

The key items that would benefit from further revision are more specifically detailed in GLDP's previously submitted materials (please see attached) and those submitted by the OPTN contractor included:

- Refinement of the proposed definitions to support uniformity in reporting.
- Refinement of data fields to elicit objective information on procurement practices and management of potential donors.
- Expansion of data fields to map the entire donation process from referral to donor potential, donor type, authorization, hospital process, and outcomes.

GLDP believes that there are opportunities for positive national change in the donation and transplantation ecosystem. To move forward on these opportunities, it is essential that there be further standardization and refinement to the data being collected and relied upon to inform OPO process improvement and comparison initiatives. We hope that the detailed recommendations that are appended here provide you with useful insights regarding how best to collect data to support performance improvement efforts.

Summary

We appreciate the efforts HRSA is undertaking to improve the organ donation and transplantation system in the United States and again thank you for the opportunity to offer these comments. GLDP respectfully requests that OMB and HRSA reconsider the previously submitted information by GLDP and other stakeholders before moving forward with the Ventilated Patient Form as proposed. We remain available to serve as a resource to you and the Agency in these important efforts to improve OPO performance and accountability and, ultimately, save lives.

Sincerely,

Richard D. Hasz
President & CEO

Attachment
Gift of Life Donor Program -2024 Information Collection Request HRSA (OMB No. 0906-xxxx-New)
(previously submitted January 3, 2025)

GIFT of LIFE DONOR PROGRAM
A Legacy of HEROES. A Future of HOPE.

January 3, 2025

Joella N. Roland, Esq.
HRSA Information Collection Clearance Officer
Room 14NWH04
5600 Fishers Lane, Rockville, Maryland, 20857
(submitted via *paperwork@hrsa.gov*)

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Re: Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New

Dear Ms. Roland:

Gift of Life Donor Program (GLDP) is privileged to serve as the designated organ procurement organization (OPO) serving the Eastern half of Pennsylvania, Southern New Jersey and the State of Delaware for 50 years. GLDP is the one of the nation's largest OPOs and has been long been a national leader. Our unparalleled success in helping save lives is only possible through GLDP's decades-long commitment to excellence and continual process improvement, fiscal responsibility and partnership with our healthcare community. The GLDP service area covers 126 acute care hospitals and 12 local transplant centers, with a population base of more than 11 million people. Over GLDP's history, we have coordinated more than 59,000 organs for transplant and our donation service area has contributed more organs for transplant than any other region of the country since the inception of the national system.

We appreciate the opportunity to provide feedback on the Health Resources and Services Administration (HRSA) Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network. We thank you in advance for your consideration of our views and recommendations and welcome a chance to partner with HRSA in advancing data collection to ensure that as many organs are transplanted as possible to maximize the number of lives saved.

Background

GLDP strongly supports HRSA's commitment to efforts to update and improve data collection to drive donation and transplantation performance. GLDP notes that the Organ Procurement Transplantation Network (OPTN) provided comprehensive comments on the Information Collection Request and the Ventilated Patient Form. The OPTN included in its response the paper "Concepts for OPOs Referral Evaluation Data Collection Process" (OPTN Concept Paper) proposing a new approach to OPTN data collection by focusing on developing a module that can be incorporated into OPO Electronic Donor Records (EDR) that includes standardized documentation of referral findings and logic to drive responses by OPO personnel during the referral evaluation process. (See OPTN Comments, page 7 and its attached OPTN Concept Paper) The contemplated module would include the capacity to electronically transfer the collected data to the OPTN.

GLDP supports the OPTN Comments and submits this GLDP feedback to provide further context and detail with regard to the advantages of a uniform tool to standardize data collection, and the use of logic and algorithms to drive OPO performance.

For over twenty (20) years GLDP has relied upon donation process and outcome data collection algorithms to drive its performance. The data collection fields and algorithm maps the entire donation process from referral to donor potential, donor type (Donation after circulatory death (DCD) versus donation after brain death (DBD)), authorization, hospital process and outcomes. It also includes data collected from missed referrals found on death record review. In fact, it is the GLDP Donor Tracking Tool which was the basis for the recommendations in the OPTN Concept Paper.

The GLDP Donor Tracking Tool fields have been designed to eliminate variation in reporting and ensure that responses are mutually exclusive. As noted in the OPTN Comments, in order to achieve the HRSA data directive goals it is critical that data fields are sufficiently clear and have the necessary granularity to avoid the risk of subjective interpretations that can increase variability in reporting across all OPOs. If listed choices are not mutually exclusive two users could select different outcomes for the same fact pattern.

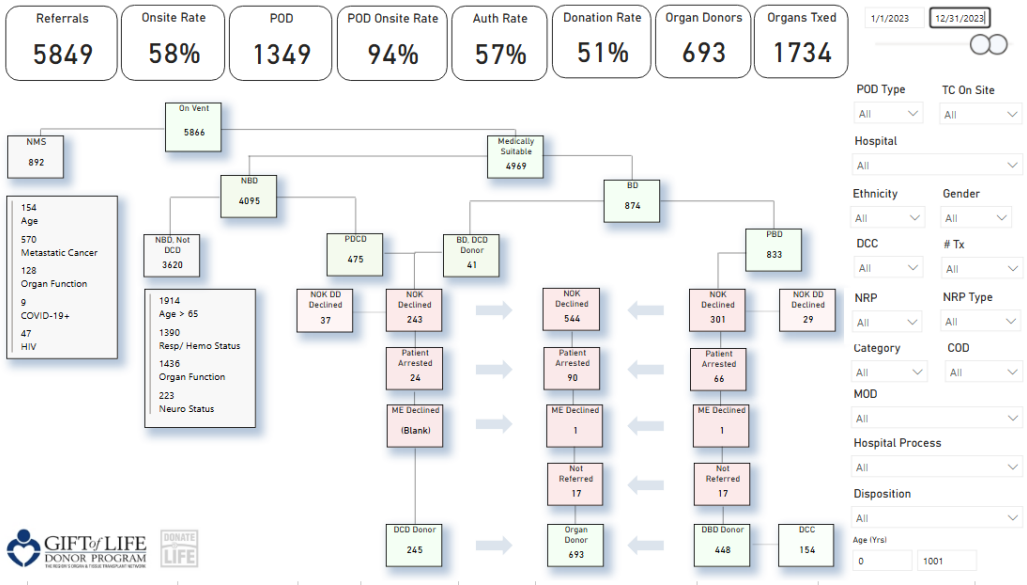
Within our own organization we have over eighty different users entering data to support performance assessment and quality improvement. The GLDP Donor Tracking Tool has been built and refined over time to provide consistency in data entry, and also to eliminate subjectivity by the user. GLDP firmly believes that an enhanced model such as the one described in the OPTN Comments can be achieved and implemented quickly (within six months) to assess and drive donation performance across the United States, regardless of region. It can also be a valuable tool to assess comparative OPO performance.

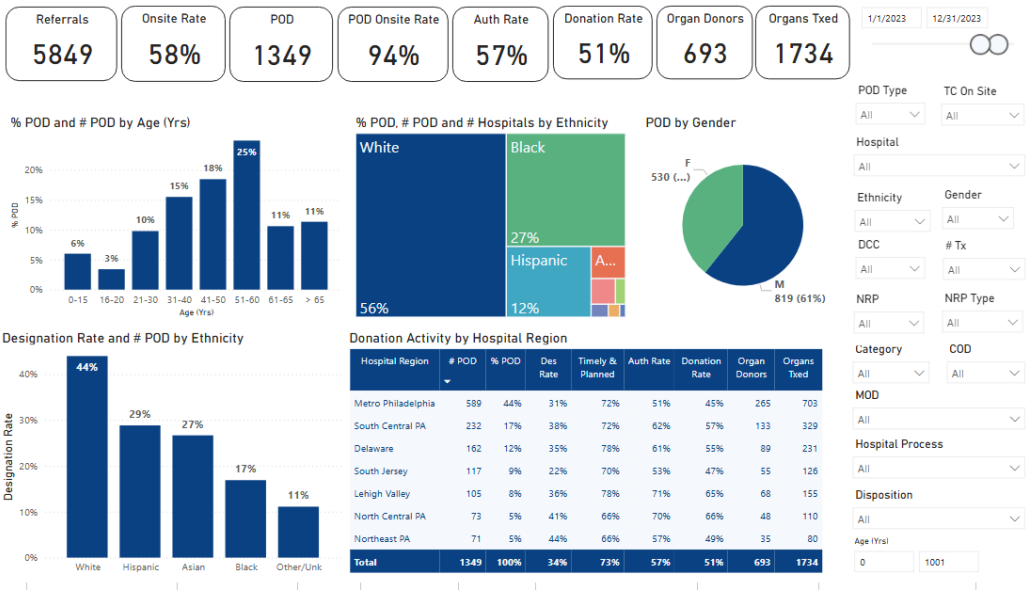
I. GLDP's Donor Tracking Tool

GLDP has been utilizing a version of its Donor Tracking Tool since at least the early 2000s. Currently the GLDP Donor Tracking Tool has over 130 fields. Logic is embedded in the electronic data collection tool (contained in the GLDP Electronic Donor Record) and users are required to complete certain mandatory fields (which for the most part are binary yes/no fields). Based upon the information inputted, the logic determines the referral outcome rather than relying on the subjective "determination" of an individual user. The fields are designed (based on the programming logic) to eliminate user variability. This is in contrast to the lack of clarity and non-exclusive fields included in the Ventilated Patient Form.

Below are sample reports for 2023 derived from the GLDP Donor Tracking Tool data. These include both outcome and process metrics. Reports generated from the Donor Tracking Tool data allow for a clear view of process breakdowns and a laser focused approach to process improvement. It also is an important tool in discerning trends in the donor population and hospital practice so that appropriate innovations and adaptations can be implemented timely.

The GLDP Donor Tracking Tool data fields include specific fields on the donor hospital process, and outcomes for all ventilated referrals. This information is invaluable in reviewing and providing on-going process improvement feedback to the donor hospital. The data can be culled to highlight performance by hospital system, individual hospital (by size/geography), and hospital unit. The feedback and patterns are then shared with the critical hospital stakeholders on a recurring basis. Importantly, and consistent with the objective for OPOs, this data also allows for hospital comparative data. GLDP finds the use of the Donor Tracking Tool data to be essential to instituting best clinical practices in each hospital setting.





Consistent with the HRSA objective that improvements to donation and transplantation outcomes be data driven, GLDP has relied upon the various iterations of data generated by its Tracking Tool to inform its practice, and its understanding of changing trends within individual hospitals, hospital systems and regionally. Year to year, month to month and other comparative data provides important insights into the healthcare ecosystem, such as hospital practices regarding OPO notification, withdrawal of support, optimal timing for family approach and allocation of resources. Examination of performance data that is inputted and recorded in a consistent manner also allows GLDP to understand and support individual team member performance in support of the donation process.

GLDP acknowledges that the logic driving its Donor Tracking Tool is specific to GLDP's organizational needs, and is likely broad in its definition of "potential" donors in order for GLDP to assess whether all donation opportunities are being explored. This may result in an over reporting of donor potential. What is particularly relevant to GLDP is its ability to rely on the standardized data sets to timely assess comparative performance from one time period to another, one hospital to another, one unit to another, and one GLDP team member to another. GLDP's track record and performance as a Tier 1 OPO has been informed by the information, trends and process improvement opportunities identified in data collected through the Donor Tracking Tool.

Attachment 1 is the current GLDP Donor Tracking Tool which highlights the fields and process points that are tracked and recorded. **Attachment 2** is an example of certain of the GLDP Programming Logic Utilized for Referral Outcomes and Process Metrics. **Attachment 3** is a rendering of a sample Comparative Hospital Profile for Regional Trauma Centers for 2023 which highlights outcome and donation process metrics. GLDP would welcome the opportunity to review these Attachments and related materials with HRSA.

II. HRSA Information Collection Request

As noted, GLDP supports the objectives of the data forms. It has significant reservations concerning the ability of the Ventilated Patient Form as constructed to achieve the cited goals. Given the lack of clarity in the construct of the definitions in the Form, the fact that fields are not mutually exclusive (OPOs will report the same referral fact pattern in multiple ways) and that OPOs don't currently capture certain of the data points suggests the implementation of the Ventilated Patient Form will promote variability in reporting by OPOs and not the needed process improvement information.

Of specific concern to GLDP with regard to the proposed Ventilated Patient Form is that:

- Definitions need greater clarity
- Data fields are not mutually exclusive.
- Data Collection can only drive process improvement if there is uniformity and standardization in the data being collected. There has been no standardized process identified or adopted for death record reviews. Instituting the collection of new data points not currently being reported to the OPTN (as contemplated in the Form), without establishing the baseline of what that process should entail will result in unwieldy, incongruent data not capable of being used to objectively drive or compare OPO performance.
- **Attachment 4** is feedback regarding each proposed data field in the Form as submitted by the OPTN in its OPTN Comments. GLDP concurs with these specific comments.

There is limited benefit from collecting data that will be reported inconsistently from one organization to another and that will not "inform" improvement or allow for comparative assessment. The following highlight a few examples of standardizations and definitions that are needed prior to instituting reporting on the newly proposed data point of hospital "interference" or death record reviews. These supplement those examples included in the OPTN Comments.

- There is no current established standard defining the concept of "hospital interference". (Note: There is not a standard definition of what constitutes a "timely" referral) Nor is there an established and uniform means for documenting the occurrence or for communicating with the hospital about that occurrence. This includes to whom the occurrence should be reported, the time frame of reporting and the subsequent action step. Additionally, as constructed, the Ventilated Patient Form would only collect "hospital interference" on cases that didn't result in donation and **NOT** deviations in the donation process that the OPO successfully overcame but nonetheless may have required the deployment of additional resources, and may have impacted the timeline of the donation process, and the scope of the recovery. Without standardized definitions and reporting processes, it is likely that the reported rates of "hospital interference" would not lead to an accurate understanding of incidence or be meaningful for comparative purposes. GLDP urges HRSA to engage in stakeholder discussions with OPOs and hospitals on this topic to further clarify the definition and to support consistent reporting.

- Without standardized protocols for death record reviews, any data being reported would not be a valid basis for comparison. This is inconsistent with HRSA's stated objective of driving and improving performance. Standards surrounding brain death potential and DCD potential do need to be established as a part of any death record review data collection process (donor age, time to death, co-morbid factors etc.).

Moving forward with the Ventilated Patient Form may frustrate HRSA's intent to advance meaningful data collection and data integrity and result in the need to reverse use of the Form in relatively short order. Instead of moving forward with the proposed Form, a more fiscally prudent investment of time and expense resulting in greater stewardship of the gifts of life would be adoption of a well- defined national collection model consistent with the OPTN Concept Paper.

III. Adopting a National Module for OPOs to Drive Improvement

In its leadership role, GLDP has initiated communication with the two (2) largest electronic donor record providers to OPOs to determine the feasibility of implementing a module as described in the OPTN Concept Paper nationally. In its inquiry regarding feasibility, GLDP focused on programming, module development, and build out, as well as the associated timeline given the urgent need for a standardized national tool with the capacity and logic to map and inform the referral evaluation process. It is GLDP's understanding that such a module could likely be incorporated within a six (6) month timeline. GLDP has reached out to AOPO and non- AOPO members and have received overwhelming support of this approach. Given this nationwide support for a data collection tool that allows for truly standardized input and reporting, and also drives consistent data collection and assures data integrity, we request that HRSA work collaboratively with the OPOs to modernize the existing data collection system.

GLDP believes that the opportunities for positive national change that the donation and transplantation ecosystem faces are significant. In order to leverage these opportunities, it is essential that there be further standardization and refinement to the data being collected and relied upon to inform OPO process improvement and comparison initiatives.

Summary

We appreciate the attention toward improving the organ donation and transplantation system in the United States and the opportunity to offer these comments. GLDP remains available to serve as a resource to you and the Agency in these important efforts to improve OPO performance and accountability and, ultimately, save lives.

Sincerely,

Richard D. Hasz
President & CEO

Attachments:
Attachment 1 -GLDP Donor Tracking Tool

Attachment 2- Example of GLDP Programming Logic Utilized for Outcomes and Process Metrics
Attachment 3 -Sample Comparative Hospital Profile for Regional Trauma Centers for 2023
Attachment 4- OPTN Comment Excerpt on Ventilated Patient Form Fields

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____
Please Check One: □ Donor □ Referred Not Recovered GLDP Referral #: _____

Hospital Information

Call Date/Time:_____ Admission Date/Time: _____
Hospital: _____ Hospital Code: _____
Unit Type: _____ Hospital Unit Name: _____
Contact Phone: _____ Extension: _____

Referring Person

First Name: _____ Last Name: _____ Position: _____

Attending Physician

First Name: _____ Last Name: _____

Additional Details for CPC Provided by Caller:

Donor Demographics

Patient First Name: _____ Patient Last Name: _____

Date of Birth: _____ □ Unknown Age: _____ □ Years □ Months □ Days UNOS #: _____

Gender: □ Male □ Female □ Unknown Race: □ African American □ Asian □ Caucasian □ Hispanic □ Indian/Sub-Continent □ Unknown □ Other: _____ Ethnicity: □ Hispanic □ Non-Hispanic

Patient Weight: _____ □ lb □ kg Patient Height: _____ □ cm □ in

Patient Address: _____

Patient City: _____ Patient State: _____ Zip Code: _____

Advanced Directives CPC must be notified before you check the registry.

Was registry accessed? O Yes O No If yes, State? _____

Did the patient have a donor designation on the registry? O Yes O No If yes, obtain hard copy for donor record.

Was donor designation on another form of Advanced Directive? O Yes O No If yes, type: O Donor Card O Living Will O Other
Type if other: _____

Was there written evidence of opposition to donation by decedent? O Yes O No If yes, specify: O Living Will O Power of Attorney O Other
Type if other: _____

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____

CPC Response – Hospital Referral Process

At the time of the initial referral:

Was the patient on a ventilator? O Yes O No If No: O Patient Extubated O Patient Never Intubated O Died on Ventilator

Date/Time of Extubation: _____

Was the referral on time for on-site GLDP family intervention? O Yes O No

Was the patient's MAP ≥ 60? O Yes O No

Patient Status at the time of the referral was: □ not brain dead, patient has some reflexes present □ patient appears brain dead

□ 1st exam c/w brain death □ 2nd exam c/w brain death or patient pronounced

□ patient was in hypothermia protocol

Prior to the **initial** referral, did the healthcare team approach the family? O Yes O No

If yes, check all that apply: □ Donation □ Withdrawal of life sustaining therapies □ Limitations of life sustaining therapies

Did the TC request a clinical intervention to preserve donation opportunity by phone prior to arrival? O Yes O No

If yes, check all that apply: □ Intervention to support hemodynamics

□ Delay of withdrawal of life sustaining therapies (i.e. mechanical support)

Did hospital staff agree to TC request? O Yes O No Name of RN/MD: _____

Explain

Did the TC request family intervention by phone prior to arrival? O Yes O No

If yes, check all that apply: □ Request for delay of withdrawal of life sustaining therapies

□ Request for clinical intervention (i.e. add pressors)

□ Request for donation

Did the family agree with request? O Yes O No

Name of family member: _____ Relationship to patient: _____

Explain

Was a coordinator dispatched to referral? O Yes O No

If yes, Coordinator dispatched to Hospital: _____ Dispatch Date/Time: _____

If no, complete Preliminary Tissue Suitability:

Does the patient have HIV? O Yes O No

Does the patient have Hepatitis B or C? O Yes O No

Does the patient have signs of current IVDA? O Yes O No

Does the patient currently have cancer? O Yes O No

If yes, cancer type: _____

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____

TC On-Site Response			
Transplant Coordinator:			
Arrival Date/Time:			
Training Case:	O Yes O No	O Yes O No	O Yes O No
Training Role:	O Orientee O Preceptor	O Orientee O Preceptor	O Orientee O Preceptor
Evaluated Donor:	O Yes O No	O Yes O No	O Yes O No
Comprehensive Review of Medical Records:	O Yes O No	O Yes O No	O Yes O No
Team Huddle:	O Yes O No	O Yes O No	O Yes O No
If Yes, Team Huddle Participants:			
Family Approach:	O Yes O No	O Yes O No	O Yes O No
Authorization Type:	O Und O Verbal O Written	O Und O Verbal O Written	O Und O Verbal O Written
Med/Soc History:	O Yes O No	O Yes O No	O Yes O No
Donor Management:	O Yes O No	O Yes O No	O Yes O No
Allocation:	O Yes O No	O Yes O No	O Yes O No
Surgical Recovery:	O Yes O No	O Yes O No	O Yes O No
TIC Staff Updated:			
CPC Updated:			
Departure Date/Time:			

First TC Dispatched Preliminary Tissue Screening

Does the patient have HIV? O Yes O No Current Tissue Eligibility: _____

Does the patient have Hepatitis B or C? O Yes O No

Does the patient have signs of current IVDA? O Yes O No

Does the patient currently have cancer? O Yes O No

If yes, cancer type? _____

Final Disposition

UNOS Categories

Type of Death: O Trauma O Non-Trauma

Cause of Death: □ Anoxia □ CVA/Stroke □ Head Trauma □ CNS Tumor □ Other: _____

Mechanism of Death: □ Drowning □ Seizure □ Drug Intoxication □ Asphyxiation □ Cardiovascular

□ Electrical □ Gunshot Wound □ Stab □ Blunt Injury □ SIDS

□ Intracranial Hemorrhage/Stroke □ Death from Natural Causes

□ None of the Available: _____

Circumstances of Death: □ MVA □ Suicide □ Homicide □ Child-Abuse □ Non-MVA □ Death from Natural Causes

□ None of the Available: _____

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____

Medical Suitability

Was the patient medically suitable? O Yes O No

If no, check all that apply: □ HIV □ Age □ Metastatic cancer □ Organ function

Organ	Reason Not Suitable
Heart:	_____
Lungs:	_____
Kidney:	_____
Liver:	_____
Pancreas:	_____

Does the patient have a history of any of the following? O Yes O No

If yes, check all that apply: □ Liver failure □ Hypertension □ Hepatitis B □ Hepatitis C

□ Positive Blood Cultures □ PHS High-risk social/behavioral history

□ Hemophilia □ Dialysis □ Cancer – any

□ Diabetes O Insulin Dependent O Non-Insulin Dependent

Terminal Lab Values: Creatinine: _____ AST: _____ ALT: _____ pO2/FiO2 _____/_____

Final Neuro Assessment

Final Brainstem Reflexes: Date/Time: _____

Pupillary Reaction:	O A	O P	O ND	Cough:	O A	O P	O ND
Corneals:	O A	O P	O ND	Gag:	O A	O P	O ND
Doll's Eyes:	O A	O P	O ND	Painful Stimuli:	O A	O P	O ND
Cold Calorics:	O A	O P	O ND	Spontaneous Breathing:	O A	O P	O ND

At the time of the final neurological assessment, did the patient appear brain dead? O Yes O No

If yes, was the patient pronounced brain dead? O Yes O No

If no, why not? □ Sedatives/paralytics □ Family declined BP/vent support □ Patient arrested □ Support w/d □ Hypothermia protocol

If the patient was pronounced brain dead:

1st Brain Death Exam Date/Time: _____ 2nd Brain Death Exam Date/Time: _____

1st Exam Performed by First Name: _____ 2nd Exam Performed by First Name: _____

1st Exam Performed by Last Name: _____ 2nd Exam Performed by Last Name: _____

Pronouncing MD/DO First Name: _____ Pronouncing MD/DO Last Name: _____

Was there a delay in brain death declaration? O No O Yes, › 12 Hours O Yes, › 24 Hours Explain: _____

Brain Death Testing Performed

□ Clinical Exam □ Apnea Test □ Cerebral Blood Flow Study □ EEG □ Other, Specify: _____

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____

DCD Evaluation

Does the patient have a primary non-neurological injury? O Yes O No O Cystic Fibrosis O Resp Failure O ALS O Spinal Cord Injury O Other: _____

Is there a supportive device in place? O Yes O No □ VAD □ ECMO □ Balloon Pump □ Pacer/AICD

Down Time (Any period associated with no cardiac rhythm and/or BP) O Yes O No O Unknown

Cardiac compressions (Pre-hospital/hospital resuscitation) O Yes O No O Unknown

Time since injury: _____ Days

Was a respiratory drive assessment completed? O Yes O No If no, why: □ Level of sedation □ Respiratory status □ Hemodynamic status □ Other: _____

If yes, time off ventilator: _____ Minutes

Respiratory Drive Assessment

Date/Time	HR	BP	RR	SPO2	NIF	Min Vent

Is the patient considered a DCD candidate? O Yes O No

If yes, Outcome: O DCD Donor O Family Declined O Patient Arrested O Attempted, did not expire

If no, check all that apply: □ Respiratory/Hemodynamic Status □ Age □ Organ Function □ Neuro status

Organ	Reason Not Suitable
Lungs:	_____
Kidney:	_____
Liver:	_____

If no: Was TC onsite for extubation? O Yes O No Did the patient die in < 1 hour? O Yes O No

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____

Authorization

Was the patient's NOK approached regarding donation? O Yes O No

If **yes**: By whom? _____ Relationship to Patient: _____

Authorization Type: □ Telephonic □ Written

Interpreter used? O Yes O No If interpreter involved, what language? _____

Did we ask the family for additional time to support the patient through brain death? O Yes O No

If no, explain: _____

If yes, did family grant additional time? O Yes O No

If no, explain: _____

If yes, duration of time granted? _____

If **no**: Reason not approached? □ Patient cardiac arrested prior to family discussion □ ME/Coroner decline

□ Gift document only utilized □ Other: _____

Did the family initiate donation discussion? O Yes O No

Was the NOK interested in **organ** donation? O Yes O No

If no, reason: □ Religion □ Timing (Not BD, Not DCD, Not willing to wait) □ Timing (wants immediate withdrawal)

□ Incision □ Intact for burial □ Decedent wishes □ Family not accepting brain death/condition

□ Other: _____

Was the NOK interested in **tissue** donation? O Yes O No O Pending Disposition

Did we move forward in opposition of family with donor designation? O Yes O No

If no, explain: _____

Was written authorization obtained? O Yes O No

If **no**: Reason not obtained: □ Patient cardiac arrested prior to family discussion □ ME/Coroner decline

□ Gift document only utilized □ Other: _____

Was ME/Coroner contacted? O Yes O No Did the ME/Coroner decline donation? O Yes O No

Approach/Request Process

The timing of the approach was: □ Before pronouncement of brain death □ After pronouncement of brain death

If before, select reason why: □ hemodynamic status □ staff mention □ decision to limit therapy □ w/d decision □ family initiated

□ other: _____

Was brain death or the grave prognosis explained by health care team to NOK prior to request? O Yes O No

1st Approach by whom? O TC O MD O RN O Other

Transplant Coordinator: _____

MD/RN/Other: _____ Title: _____

2nd Approach by whom? O TC O MD O RN O Other

Transplant Coordinator: _____

MD/RN/Other: _____ Title: _____

Did GLDP coordinator approach family after family had initially declined to hospital staff? O Yes O No

If no, why? _____

Members of the hospital care team present during the Authorization conversation (check all that apply):

□ None □ RN □ MD □ Pastoral Care □ Social Work □ Other: _____

ATTACHMENT 1- GLDP DONOR TRACKING TOOL

GIFT OF LIFE DONOR PROGRAM

Organ Donor Tracking Tool (DTT) Patient Name: _____

Cardiac Arrest

Did the patient arrest? O Yes O No Date/Time of arrest: _____

If yes, patient arrested prior to (check all that apply): □ Referral □ Arrival □ Pronouncement □ Approach □ Recovery

Circumstances of arrest: □ Despite maximum resuscitative efforts, patient cardiac arrested

□ Hospital withdrew support prior to approach

□ Hospital limited therapy prior to approach

DTT Sign-Off

Organ Referral Disposition: _____ Current Tissue Eligibility: _____

AOC/CPC updated, TIC updated with disposition and tissue screening/family dynamics reviewed with the TIC.

TC Signature: _____ TC Date/Time Signed: _____

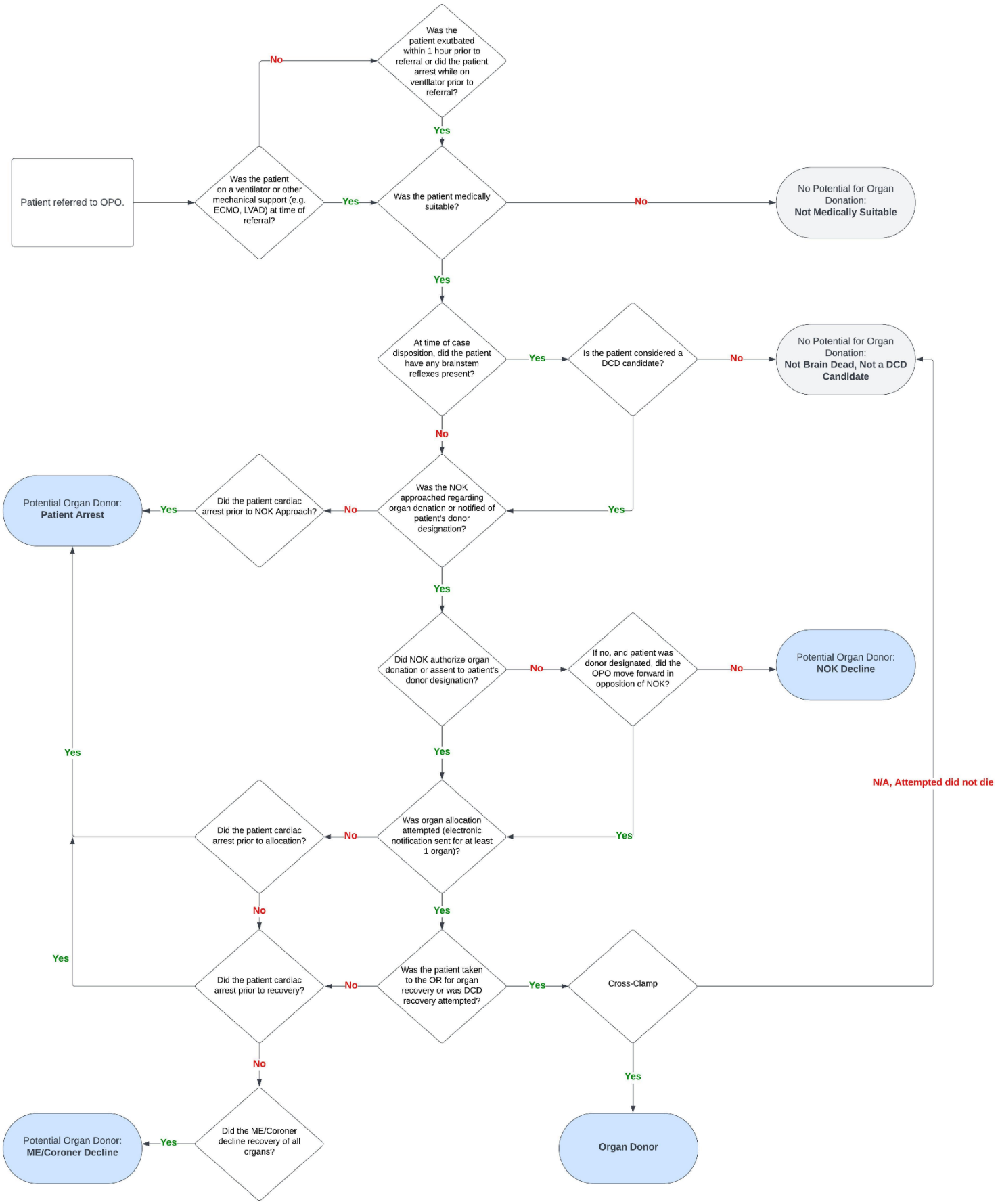
Tissue screening/family dynamics reviewed with TC.

TIC Signature: _____ TIC Date/Time Signed: _____

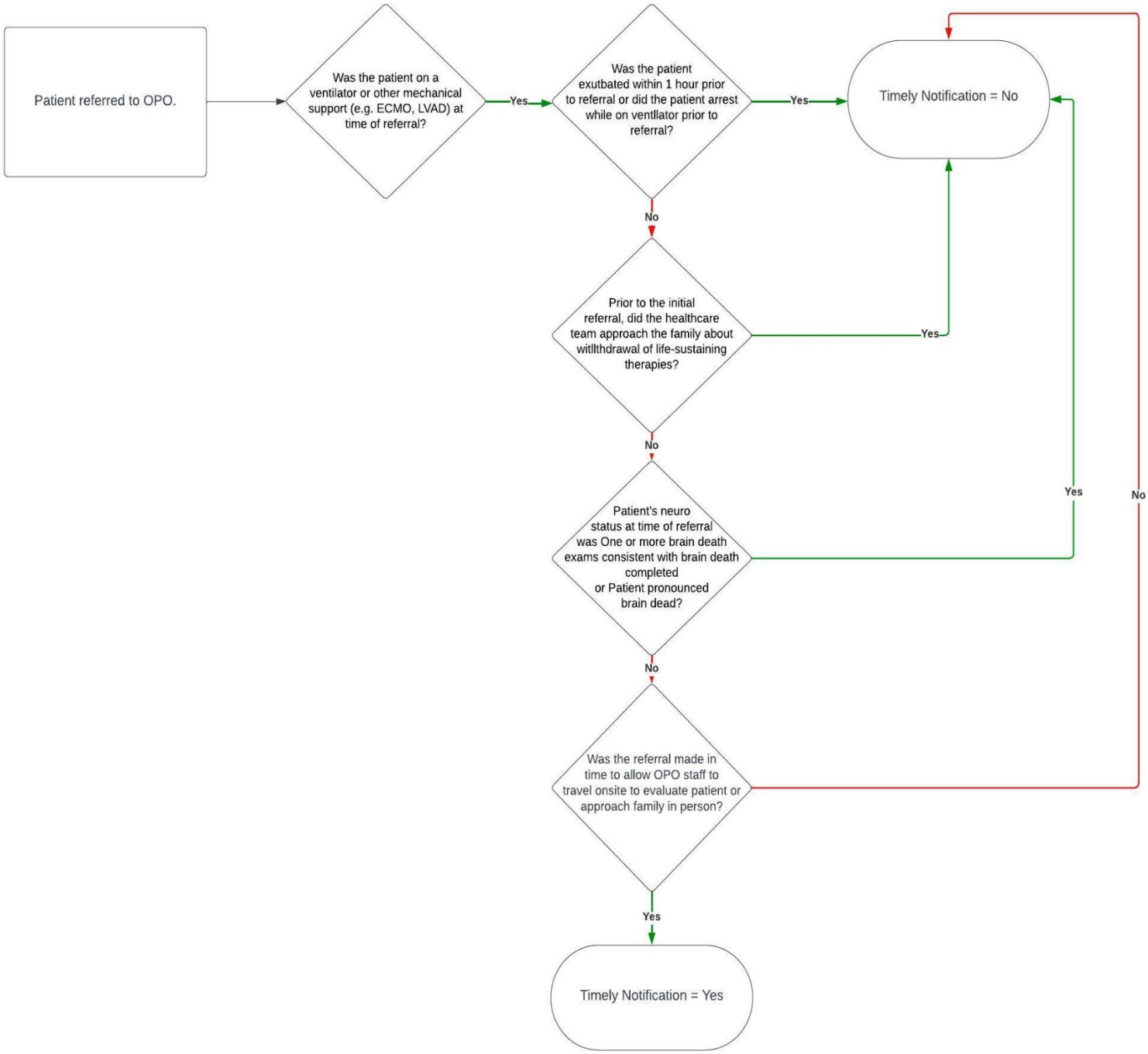
Preliminary research suitability: O Yes O No

AOC: _____ Date/Time Case Complete: _____

ATTACHMENT 2- Example of GLDP Programming Logic Utilized for Outcomes and Process Metrics



ATTACHMENT 2- Example of GLDP Programming Logic Utilized for Outcomes and Process Metrics



ATTACHMENT 3 - Sample Comparative Hospital Profile for Regional Trauma Centers for 2023

Comparative Hospital Profile
Regional Trauma Centers
Ranked By Conversion Rate
2023

Hospital Name	# POD	OUTCOME METRICS			PROCESS METRICS			
		# Organ Donors	Conversion Rate	Transplant Rate (O/E)	Referral Rate	Timely Notification Rate	Planned Approach Rate	Timely & Planned Rate
St. Mary Medical Center	10	7	70%	1.24	100%	100%	89%	80%
Christiana Hospital	86	56	65%	1.06	100%	94%	96%	88%
Paoli Hospital	9	5	56%	1.24	100%	89%	88%	67%
Thomas Jefferson University Hospital	40	21	53%	1.08	98%	85%	87%	68%
Jefferson Torresdale Hospital	34	17	50%	1.18	98%	88%	100%	82%
Crozer-Chester Medical Center	28	14	50%	1.13	96%	93%	88%	71%
Penn Presbyterian Medical Center	43	20	47%	0.93	98%	93%	90%	77%
Abington Hospital – Jefferson Health	25	13	47%	0.96	100%	92%	83%	72%
AtlantiCare Regional Medical Center - Atlantic City Campus	32	14	44%	1.09	100%	88%	80%	63%
Lankenau Medical Center	28	12	43%	1.16	96%	100%	81%	75%
Temple University Hospital	112	47	42%	1.04	100%	96%	89%	76%
Bayhealth Hospital - Kent Campus	26	8	31%	1.34	92%	92%	78%	62%
Einstein Medical Center Philadelphia	54	16	30%	1.19	100%	93%	92%	76%

ATTACHMENT 4- - OPTN Comment Excerpt on Ventilated Patient Form Fields

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Ventilated Patient Form – Field and Instructions Feedback

Many of the data elements on the VPF would not be available for all patient referrals due to how far the patient progressed in the donor evaluation process resulting in submission of 'unknown' values. Limited data is gathered when there is a clear reason to rule out a patient early in the process versus a more complete VPF submission for a patient where the OPO goes on-site or accesses the patient's medical record remotely.

Field Label	Feedback
Home Zip Code	• Recommend that the instructions include a note to not report the hospital zip code in this field and choose "Unknown" if the patient's home zip code is not known. • Include an instruction of what to enter if patient does not live in the United States. • Likely that the data will be reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
Race	• Recommend assessing the priority of updating race data collection to the recently issued OMB standard. Concerns about current data collection not addressing bi-racial and multi-racial categories. • Likely that the data will be reported as "Race Not Reported" for patients that are ruled out early in the donor evaluation process prior to OPO going on-site or accessing medical record.
Gender Identity	• Recommend removal of this data element as it is o Inconsistent with the pre-waitlist forms and other OPTN data collections. o This information is not consistently collected by donor hospitals. o Gender identity has no clinical relevance to organ donation and transplantation. • Likely that the data will be reported as "Unknown" for patients that are ruled out early in the donor evaluation process prior to OPO gathering information from legal next of kin.
Height	• Likely that the data for majority of patients will be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO going on-site.
Weight	• Likely that the data for majority of patients will be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO going on-site.

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Field Label	Feedback
	• Requiring gathering of weight for these patients will pose significant time and financial cost burden.
Age	• Recommend consistency with other OPTN data collection that includes date of birth, if available, that will calculate age and age be collected only if date of birth is unknown. • Recommend inclusion of option for unknown for patients that have not been identified.
HIV Status	• Requests clarification for why HIV status is being collected and no other relevant serologies, especially when HIV positive status is no longer an absolute rule out. • Suggest removal of this field and only collect for donors given the sensitivity of this information and that HIV is not an absolute rule out for donation.
Did patient legally document their decision to be an organ donor?	• Request clarifying the instructions regarding cascade to the Date and Time of Pronouncement of Death in the event of a No response to this question. • Most responses will likely be reported as "Unknown" as most patients are ruled out early in the donor evaluation process prior to OPO accessing registries or DMV records.
First Person Authorization Restrictions	• Request clarification on what should be the definitive sources for these restrictions. • Suggest removing tissue as an option as tissue authorization is not relevant to the organ donation process and not within OPTN scope.
Date and Time of Pronouncement of Death	• As noted in feedback for population definition, suggest completion of form and collection of this data element only when patient died within a set time after extubation where there was a potential for donation. Over 80% of referrals are not dead at time of referral and a large portion of those are ruled out for both organ and tissue donation. These patients may not die for days, weeks or even months later or potentially not die. Requiring date and time of death for all these patients is a significant cost burden that provides little value for improvement of the donation process. • Date and time for death of a referred patient that was ruled out for both organ and tissue donation early in patient evaluation will be unknown. • Suggest replacing "pronouncement" with "determination" because official pronouncement of death sometimes is done much later.

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Field Label	Feedback
	• Suggest inclusion of additional question to gather whether the patient experienced a neurologic death or a circulatory death
KDPI (not required field)	• Recommend removal of this field for the following reasons: o Optional data collection o The raw data needed to calculate the KDPI would not be available for non-donors since much of the data needed to accurately calculate KDPI comes from a medical/social history collected from the legal next of kin and testing which is conducted on a small fraction of patients. o The calculation of KDPI is done by the OPTN Computer System and not by OPOs for donors. The KDPI for registered donors can be provided by the OPTN. o The KDPI changes as additional patient information is collected. • If this field is retained, recommend changing it to KDRI rather than KDPI given that the KDPI is calculated based on a reference to all recovered donors from the prior year.
Primary Insurance (not required)	• Since this field is not required, recommend that it be removed. • This information is not captured by OPOs for ventilated patient referrals or donors. • Concern that collecting this information from the donor hospital could impact the relationship between hospital personnel and OPOs as it is highly sensitive information and it has no effect on the donation process or OPO performance. • For these reasons, it is likely to be reported as “Unknown” for most patients.
Date of Death Record Review	• Suggest moving the “Date of Death Record Review” and the “Date and Time of Hospital Referral” fields to follow the “How did the OPO learn of this patient” field for better flow of the form. • Recommend that the scope of death record review be defined and standardized to produce consistent, quality data as there is variability in how death record reviews are performed.
Was the patient referred by the hospital to the OPO?	• Recommend removal of this field as it is duplicate of the “How did the OPO learn of this patient?” field.

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Field Label	Feedback
Date and Time of Hospital Referral	• Suggest moving the "Date of Death Record Review" and the "Date and Time of Hospital Referral" fields to follow the "How did the OPO learn of this patient" field for better flow of the form. • Recommend clarifying instructions to provide guidance on how to document patients referred by one hospital and transferred to another, including patients that were referred and closed and then referred again by the same hospital or a different hospital.
Remote EMR Access	• Clarification requested on what this field is intending to collect - did the OPO have remote access to the hospital EMR or did the OPO accessed the hospital EMR remotely for this patient? • Remote access to hospital EMRs is determined at the hospital level or by OPO staff user, not on a patient level. • There are also varying levels of remote EMR access granted by hospitals. • Clarification of the instructions is requested as to whether this is a child question when the OPO responds "No" to the "Did the OPO respond onsite at the hospital to the patient referral" or is to be entered for all referred patients.
Advance Directive	• Clarification is requested as to whether this would be collected only as the source of first-person authorization or objection to donation, used in determining the appropriate LNOK decisionmaker, or if an advanced directive on end-of-life care such as withdrawal of care exists.
Patient Record Type	• Clarification is requested in the instructions to provide guidance on at what point in the evaluation this should be determined – at time of referral or at time of case disposition since eligibility changes as more patient information becomes known about the patient or the patient's condition changes • Suggestion that the field label be changed to "Donation pathway" or "Pathways being considered for donation"

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Field Label	Feedback
Was the patient medically ruled out by the OPO prior to approach?	• Recommend a standardized definition of the criteria for a medical rule out and more granular data be collected on the reason a patient is medically ruled out for use here and for the case disposition of "Medical Rule Out." • Clarification requested of the meaning of the term "prior to approach" and what is expected if the patient is ruled out after the legal next of kin is approached, either before or after legal donation authorization is obtained.
Family Objection	• Clarification of how this field should be completed when there is first person authorization and an objection from legal next of kin. • Recommend that "family" be replaced with "legal next of kin" in the field name.
Date and Time of First OPO Hierarchy Approach for Authorization	• Request for definition of "first" in the instructions. • Request that instructions be revised to request "time of approach" rather than "time of OPO onsite response" which could be via telephone or onsite.
Authorization	• The options provided in the instructions require clarification. Regardless of whether the hospital discusses donation with the legal next of kin, the OPO will discuss with legal next of kin and get legal authorization. • Clarify whether response to this question is dependent on documentation of authorization. • Suggest adding an option of "Undecided" as authorization may have been requested at time of case disposition but the legal next of kin may not have decided whether to authorize.
Tissue Authorization	• Suggest removing this field as it is not relevant to the organ donation process and not within OPTN scope. • If the field is retained, an additional option for ruled out for tissue donation should be added and clarification on what would be included in tissue, for example eye dispositions, and categories of tissue since may get authorization for some types of tissue and not others.
Case Disposition	• Request definitions for each of the disposition options be included in the instructions. • Clarification if the disposition options are mutually exclusive and if so, define when each option should be used to the exclusion of others. For example, hospital interference can occur at same time as other dispositions on the option list.

ATTACHMENT 3- - OPTN Comment Excerpt on Ventilated Patient Form Fields

Field Label	Feedback
	• Suggest adding "wardens" in addition to ME and Coroner, since the warden can decline when the patient is in custody at time of death. • Request clarification for appropriate case dispositions to use for ventilated patients found on death record review. The only disposition that appears to apply is Hospital Interference so should this be the default?
Describe Hospital Interference	• Suggest replacing the term "interference" with a less harsh term as use of interference could damage relationship with donor hospitals • Concern that reporting hospital interference to OPTN and CMS could damage OPO relationship with donor hospitals. • Clarification requested as to when a response to this question is needed – only when the interference is an outcome that was the cause for no donation or anytime there is hospital interference reflecting opportunities for improvement in hospital process. • Request specific definitions and clarifications of the options. o Referral made outside timely requirement – Should this be completed for every non-timely referral or only those that result in inhibition of donation. OPO definitions of timely referral vary so will limit the use of the data for comparison purposes o Ventilated Patient Not Referred to the OPO – there is no medical or age criteria defined for use by OPOs to identify ventilated patients with donation potential on death record review. o Unplanned Extubation After Referral Made to OPO – hospital may have planned extubation but not communicated it to the OPO or hospital may not have planned the extubation and not communicated it to the OPO. o Hospital Blocked OPO Approach for Authorization – clear definition is needed here. • Suggest Ventilated Patient Not Referred to the OPO autofill for ventilated patients identified on death record review. • Suggest additional options: o Hospital approached, family declined, OPO unable to talk with family

Field Label	Feedback
	o Hospital declined to medically treat o Patient appeared brain dead but testing not completed o Patient Transitioned to Comfort Care Before Referral Made to OPO – family may transition to comfort care only but not extubated
Report Provided to Hospital and Report to Hospital Accepted	• Concern these fields carry a significant burden by individual case and require a change in process since OPOs generally formally document reports on a monthly or longer cadence and not by individual case. • Clarification requested for if reports are required only for those cases where it inhibited donation; what constitutes a report, verbal or written; who at hospital specifically should receive report for it to be considered provided to the hospital; what constitutes acceptance by the hospital; how the hospital will demonstrate or document acceptance or rejection of the report. • Clarification is needed for the expected time frame for reporting of these fields as may not be available in the same time frame as other data requested on the form.
Remediation Plan Provided to Hospital and Remediation Plan for Hospital Accepted	• Concern these fields carry a significant burden by individual case and require a change in process since OPOs generally formally document improvement plans on a monthly or longer cadence. • Suggest replacing “remediation” with less harsh term such as “Improvement Plan” • Clarification requested of definition of "remediation plan;" if plan is required only for those cases where it inhibited donation; what constitutes a remediation plan, verbal or written; who at hospital specifically should receive report for it to be considered provided to the hospital; what constitutes acceptance by the hospital; how the hospital will demonstrate or document acceptance or rejection of the remediation plan.
Date and Time Case Close	• Clarification required of the definition of “case close.” A case has many end points depending on the disposition and the regulatory requirements governing it. For example, would the case close date and time be when the OPO has ceased external contact in the

Field Label	Feedback
	case (hospital partners, legal next of kin, etc.), when the last necessary field is completed in the OPO EMR, or when the case is required to be reported to the OPTN. How is this determined for patients identified on death record reviews?
Fields for which no field-specific feedback is provided	• Status • DonorNet Donor ID • OPO Record ID • Case detail/How did the OPO learn of this patient? (remove “Case detail/” from field name • OPO • Patient Hospital • Last Name • First Name • Middle Initial • Birth Sex • Ethnicity (comment in Additional Feedback) • Cause of Death (comment in Additional Feedback) • Mechanism of Death (comment in Additional Feedback) • Circumstance of Death (comment in Additional Feedback) • OPO Onsite Response • Date and Time of OPO Onsite Response • Method of Authorization Used by OPO • Approaches • Modality of First Approach • Language of First Approach • Interpreter for Approach • Date and Time of Authorization Obtained