S.L. Gimbel Fund administered by Inland Empire Community Foundation
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UNOS Labs, an endeavor by UNOS to research innovation solutions for system-level issues in organ transplantation, began with a single project in 2017, and quickly expanded in mid-2018 to include an entire portfolio of projects. UNOS also invested in the addition of a Data Science team to the organization in 2018, supporting the data science pillar of UNOS Labs along with other corporate goals, and added dedicated staff resources to the UNOS Labs initiatives. Today, UNOS Labs is a robust experimental incubator that brings together data, technology, and industry expertise to test and develop new products and ideas for insights to improve the system.

The projects completed by UNOS Labs are a powerful example of UNOS's commitment to innovating how we analyze, evaluate and continuously improve the national transplant system to save more lives. Designed to address bigger questions in transplantation and capitalize on existing innovations, the following projects (in addition to Organ Tracking, SimUNet^{SM} and Liver Paired Donation detailed throughout this application) have created something that benefits both the system and the patients.

- **Understanding Cold Ischemic Time (CIT):** Time is of the essence when it comes to matching a donated organ and a waitlisted patient. Cold ischemic time (CIT) is the time an organ spends outside the body between procurement and transplantation. It is a critical limiting factor in organ allocation. Each organ has its own CIT limit, ranging from four to six hours for hearts and lungs, up to 24 to 36 hours for kidneys. CIT not only limits how far an organ can travel, but prolonged CIT is also linked with higher rates of organ rejection, post-transplant complications, or donated organs being rendered non-transplantable. To better understand the drivers of CIT, UNOS partnered with OPOs and their couriers to collect key data points in the CIT continuum. Prior to this project, it was assumed that longer distances, and therefore higher transit time, increase CIT. Data collected during this project indicate that transit time is not the primary driver of CIT. It appears that OPO and transplant hospital practices are, in fact, the primary drivers for overall CIT. Our results are important because, regardless of transportation method (i.e. driven vs. flown), there was little correlation between transit time and total CIT, which challenges conventional wisdom that transportation is a primary cause of prolonged CIT in kidney transplantation.

  The project team also partnered with the policy development team to support data collection from transplant hospitals and OPOs to help further understand the various elements of CIT. These data include transplant time and times that an organ is pumped on a perfusion device (used to replicate the conditions inside the body and expand the organ's viability). Combining these data elements would allow us to better understand, on a national scale, the drivers of CIT and identify real opportunities to decrease CIT and improve outcomes for patients nationwide. These findings also support the development of allocation policies that more equitably allocate organs across the country, moving organs further to get them to the most critical patients. This information could also help drive practice changes within OPOs and transplant hospitals that could demonstrably

decrease CIT for donated organs. The results of this effort will be published in the Journal for the American Medical Association (JAMA) Network Open in December 2021.

- **Image Sharing:** A key component of organ offer decision making revolves around the availability of diagnostic images. These include images such as raw photos, radiographs, bronchoscopies, and echocardiograms. In 2018, DonorNet, UNOS' technology platform for offering and accepting donated organs, supported image sharing, but limited by file size and type. High resolution, quality images and several file types used in organ offer evaluation were not supported. The primary method of sharing images was through third party image hosting providers, directly mailing CDs of images, or sometimes even the cursory text message on a personal cell phone or email. These methods were unreliable, costly, incompatible with one another and not always secure. UNOS released a pilot of a secure Image Sharing platform within DonorNet, partnering with Ambra Health, and six OPOs across the country to test a solution that could share high-quality medical images in a consistent, efficient, and safe manner. This was a major integration effort, and pilot sites provided ideas for enhancements and improved functionality. After a successful pilot, the Image Sharing service is now available at no-cost for the transplant community to securely share medical images and improve organ offer decision-making. It is now being used at almost all OPOs across the United States and will soon complete national rollout.

II. Project Information:

A) Statement of Need

1. Specify the community need(s) you want to address and are seeking funds for.

While the number of lifesaving transplants performed in the U.S. since UNOS' inception is nearing one million, 20 people still die every day waiting for a second chance at life. Despite the miraculous success of transplantation, and the remarkable results, there are still more lives at stake and more ways to continuously improve the transplant system. Today 106,738 children, women, and men are waiting for a lifesaving organ. Their very lives depend upon an innovative, strong and efficient transplant system to find and match them to a donated organ.

The Procurement and Match Process

Organ donation and transplantation is a complex process, requiring the expertise and collaboration of thousands across the country every day. The National Organ Transplant Act of 1984 established the Organ Procurement and Transplantation Network (OPTN), for matching donor organs to waiting recipients. The OPTN is managed by UNOS, and all 57 OPOs across the country use UNOS' proprietary computer system to match and place the organs that they procure. UNOS provides tools, resources, and expertise to help OPOs improve the quality of service they provide, in order to achieve our joint goal of placing donated organs equitably and efficiently to save more lives.

In the case of both living and deceased donors, vital information including blood type, height, weight, and zip code are entered into UNet^{SM}, UNOS' secure web-based transplant platform linking all OPOs and transplant hospitals, which then initiates the matching process with potential recipients. UNet^{SM} is accessible to the transplant community 24 hours a day, seven days

a week, with organ placement specialists in the UNOS Organ Center available around the clock to answer questions and assist with organ placement.

Transplant hospitals evaluate extensive medical testing as well as a patient's mental health and social support system to determine whether or not to add a patient to the national waiting list that UNOS manages. When a transplant hospital accepts a patient as a transplant candidate, it enters medical data such as the person's blood type and medical urgency into UNet^{SM}.

Each time an organ becomes available, using organ-specific allocation algorithms derived from OPTN allocation policies and the combination of donor and candidate information, UNet^{SM} generates a match run, a rank-order list of candidates to be offered each organ. The candidates who appear highest in the ranking are those who are in most urgent need of the transplant, and/or those most likely to have the best chance of survival if transplanted. Patients' transplant physicians may accept or decline organ offers based on cold ischemic time (CIT), the donor's age or medical history and many other factors.
For every successful match, the OPO facilitates authorization, testing, the recovery of donor organs and delivery to the transplant hospital.

Improving Organ Transportation Logistics
Despite the lifesaving work of the transplant system, there is no single national transportation system to move donated organs to transplant hospitals. Transplantation is a complex network of transplant professionals, recovery hospitals, OPOs and UNOS, and moving organs results in many logistical challenges.

Organs with longer cold ischemic time (CIT, or time outside of the body), such as kidneys, often rely on the inconsistent commercial flight system. This is challenged by delayed flights, missed connections, or the rare but terrible circumstance when an organ is not loaded onto the flight. In addition, organs are moved on commercial flights through the cargo system. In cargo, the ability to add an organ to a flight is reliant on an open cargo office, and these "cargo hours" differ by airline, by airport, and can change without notice. The arrival of an organ to a closed cargo office means it cannot be loaded onto the flight or picked up by a courier, resulting in organs accruing potentially dangerous CIT with no remedy but to wait. Understanding the impact of these issues is further complicated by the fact that each OPO and transplant hospital is responsible for obtaining its own travel solutions, and in doing so, there is no centralized method to collect data about delays or to identify best practices and process efficiencies.

In contrast to kidneys, organs with greater time limitations such as livers, lungs, and hearts often move via charter flight. Though more reliable and controlled than the commercial flight system, charter flights have their own unique challenges. One such problem is that OPOs and transplant hospitals, responsible for their own transportation solutions, rely on their own established relationships with couriers and charter providers. The search for a charter flight includes calling multiple trusted companies, checking plane availability, finding pilots with available flight hours who are also available when the organ will be ready to move, and negotiating rates independently. This is a very manual process, and there is no transparency into the costs of charter flights, so there is no accountability to keep costs low. These greater expenses create a

financial strain for transplantation that trickles down to patients, especially as we seek to share organs more broadly with the sickest patients.

In addition, without real time tracking, it is difficult to identify the terrible circumstance of an organ missing a flight connection or being left behind at an airport. Retroactive analysis of organ transportation between 2014 and 2019 found nearly 170 organs could not be transplanted and almost 370 endured "near misses," with delays of two hours or more, after transportation problems. Overall, about 7% of shipments handled by UNOS from July 2014 to November 2019 encountered transportation problems. While these tragic set backs are not common and the vast majority are attributed to commercial airlines or logistics providers, a mistake like losing an organ means someone might lose their life. In response, UNOS is integrating organ tracking technology to ensure that the precious gifts of life entrusted to us by selfless organ donors get to the right patient at the right time.

Over the course of 18 months, beginning in January 2020, UNOS Labs piloted and subsequently released the Organ Tracking Service integrated into TransNet, our proprietary system for packaging and labeling organs. Partnering with tracking provider GEGO, Inc., this solution provides visibility into where organs are in transit and notifications about key milestones, including if an organ is still at an airport after the scheduled flight has taken off. Also in 2020-21, UNOS Labs tested the Travel App, an Expedia-like system designed specifically for the needs of organ transplant, to identify all available travel options. However, there is much more to do to make us the best stewards of the gift of life.

UNOS has several projects in flight to address these varied issues with organ transportation and logistics. Improved logistics systems and technologies, which UNOS is best positioned to provide in a centralized way, will make getting the right organ to the right patient as timely and efficiently as possible. It will also help collect the data necessary to identify additional improvements to the system and understand how our efforts make the system better. The Gimbel Foundation's support for this portfolio of work will strengthen the U.S. organ transplantation system by decreasing logistical barriers, increasing transparency, and making certain that every organ arrives where it needs to at the right time for transplantation.

Proven Success

Before organ tracking, there was no way to know where an organ in transit was at any given time. Here is just one example how these applications and the new system are saving lives:

> *The UNOS F.M. Kirby Foundation Organ Center (OC) staff are onsite 24-hours a day, 365 days a year. They played a key role in the pilot phase by keeping track of organs in transit and testing the new technology. As an OC staff was routinely following the progress of a kidney, they noticed the courier was heading in the wrong direction and the flight to deliver the organ was leaving in 40 minutes. The OC staff immediately called the courier, "Hello, I am with the UNOS Organ Center. I see that you are heading in the wrong direction from your route to the airport to deliver a life-saving kidney. Are you aware of this?" The courier was unaware of the precious cargo they carried and they were headed to pick up another package. They immediately turned around – something*

the OC staff could see in real time – and headed straight to the airport. The courier made it and got the organ on the plane right before the doors closed, literally saving a life!

B) Project Description

1. Describe your project. How does your project meet the community need?

UNOS is committed to honoring and protecting the precious gift of life. Our UNet[SM] system collects data on donors and patients awaiting a transplant, and uses an algorithm to match organs to patients in the safest and secure method possible. TransNet, within UNet[SM], is a system created to package and label organs for transportation to ensure that the right organ goes to the right patient. A diverse and highly informed network of staff and professional volunteers create and analyze the policies that drive organ allocation for clinical relevance, equity and fairness. However, logistics – moving the organ from recovery hospital to transplant hospital – is an opaque space. UNOS aspires to create a robust and advanced transportation and logistics toolkit in which zero organs are discarded due to transportation issues. Two key efforts, the modernization of our Organ Tracking solution with better technology and transparency, and the deployment of a Travel App to quickly put route options and estimated times of arrival in the hands of the OPOs, promise to help us reach this goal. With the support of the Gimbel Foundation, together we can bring these projects to life and ensure that every donated organ reaches the right recipient and at the right time.

{Project details removed.}

2. What is unique and innovative about this project?

UNOS is implementing existing, and proven, tracking technologies and bringing best practices from industry experts to create a customized solution for the singular needs and unique challenges of organ transportation and logistics. Transporting organs is far more sophisticated and complex compared to transporting goods, and the solution needs to not only ensure the safety of the organ but provide ease of use, and time-saving tools for the individuals working around the clock to find the right transportation for a precious donated organ. With these building blocks, we are saving more lives faster and ultimately reducing CIT, thus helping to improve patient outcomes post-transplant.

This project brings together a suite of initiatives, subject matter experts, and community collaborators to solve the biggest logistical problems facing organ transplantation. UNOS is home to the experts in the organ transplantation system, and brings that depth of knowledge to creating solutions that can be implemented system-wide. UNOS is also uniquely positioned to integrate initiatives in a way that make them easier to adopt for OPOs and transplant hospitals, and to bring together transplant experts in focus groups, pilot testing, and other forums to get their input on how to build solutions that will meet their needs. In addition, these projects engage true subject matter experts in logistics and transportation to ensure that from a technology perspective, we are bringing innovative and transformational solutions to transplant and can continue to stay on the cutting-edge of any tool, product or service released to the community.