

## *Guidance Document for Public Comment*

# Guidance for Data Collection Regarding Classification of Citizenship Status

*OPTN Ad Hoc International Relations Committee*

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# Guidance for Data Collection Regarding Classification of Citizenship Status

*Sponsoring Committee:* Ad Hoc International Relations  
*Public Comment Period:* August 3, 2021 – September 30, 2021

## Executive Summary

The OPTN Ad Hoc International Relations Committee (hereinafter “the Committee”), in its role as advisory to the OPTN Board of Directors, proposes a guidance document to address the classification of citizenship status in OPTN data. The citizenship status data element is collected on the Transplant Candidate Registration (TCR), Living Donor Registration (LDR), and Deceased Donor Registration (DDR) forms, which are submitted by transplant programs and organ procurement organizations (OPOs) upon the registration of all organ transplant candidates, living donors, and deceased donors. The data collected from the citizenship status field is utilized for monitoring patient safety and analyzing trends to inform the development of evidence-based policies. The citizenship status data element presents unique challenges for transplant programs and OPOs that capture and report due to differing interpretations of the various citizenship status categories. Upon review of current data and literature, as well as a member request for guidance, the Committee decided that guidance on the citizenship status data element was needed to promote accurate data collection. The proposed document seeks to provide guidance in order to improve data collection by addressing accurate classification of citizenship status at registration as well as accurate, complete, and timely follow-up data collection in regards to citizenship status.

## Background

Throughout this document the term ‘citizenship status’ refers to the OPTN data collection element “citizenship status”. This OPTN data element collects information on citizenship, residency, and country of origin. It is not within the OPTN’s function to discern legality of immigration status of patients. Therefore, statements and guidance within this document focus solely on accurately collecting citizenship status as it pertains to OPTN data collection.

The Committee is charged by the OPTN Board of Directors with reviewing issues related to non-U.S. citizens/non-U.S. resident (NCNR) transplant patients. The Committee works within this charge to address topics related to NCNR patients who enter the U.S. for transplant as well as U.S. candidates who seek transplant in other countries. In order to accurately review emerging issues as well as make informed decisions, quality data is essential for the Committee.

*OPTN Policy 17.1.C: Report of Activities Related to The Transplantation of Non-US Citizens/Non-US Residents* requires the Committee to “prepare and provide public access to an annual report of transplant hospital activities related to the registration and transplantation of non-US citizens/non-US

residents.”<sup>1</sup> The Committee has sought to bring transparency to activity related to NCNR transplant patients through review of their annual data report, as well as data collection changes.<sup>2</sup> The Committee continues to bring transparency to NCNR patient transplant activity by proposing a document to further guide the transplant community on the OPTN citizenship status data element in order to improve accurate data collection.

The OPTN collects citizenship status on transplant candidates, living donors, and deceased donors. The citizenship status data element is the sole data element that allows the OPTN to review citizenship, residency, and country of origin of its patient and donor population, pursuant to OPTN Policy.<sup>3</sup> The collection of these data elements lends to gathering demographic data on patients, and enabling health care professionals appropriately plan, with the intent of improving follow-up data submission rates.

In 2011, the OPTN Board of Directors approved changes to the citizenship status data collection field, a data collection proposal sponsored jointly by the Committee and the OPTN Ethics Committee. The Committees were interested in quantifying the number of individuals who travel to the U.S. for transplant in order to understand the magnitude of “transplant tourism”, as outlined in the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*.<sup>4</sup> The Committees’ interest in quantifying transplant tourism was to better analyze whether the U.S. was impairing its ability to provide transplants for its residents due to NCNR patients entering the U.S. to undergo organ transplantation from deceased organ donors.<sup>5</sup> The proposal deleted the term “alien” and proposed the terms “resident and “non-resident”, as residency is important to understand transplant tourism within the U.S.<sup>6</sup> The citizenship status data collection changes (Table 1) were implemented in UNet in 2012.<sup>7</sup>

The UNet<sup>SM</sup> Help Documentation definitions were updated in conjunction with the citizenship status data element change. The main distinction to note is that, prior to the data elements changes in 2011, residency was previously based on legal immigration status, whereas, post 2011 changes, it is defined as where the patient considers their primary place of residence.<sup>8</sup> The following are data definitions for the citizenship status data element as they currently appear in UNet Help Documentation<sup>9</sup>.

- **U.S. Citizen:** A United States citizen by birth or naturalization.
- **Non-U.S. Citizen/U.S. Resident:** A non-citizen of the United States for whom the United States is the primary place of residence.
- **Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Reason Other Than Transplant:** A non-citizen of the United States for whom the United States is not the primary place of residence, and who came to the U.S. for a reason other than transplant.

<sup>1</sup> OPTN Policy 17.1.C, *Report of Activities Related to The Transplantation of Non-US Citizens/Non-US Residents* (June, 2021).

<sup>2</sup> 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

<sup>3</sup> OPTN Policy 17.1.B: Review of Non-US Citizens/Non-US Residents, and 17.1.C: Report of Activities Related to the Transplantation of Non-US Citizens/Non-US Residents.

<sup>4</sup> Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: The Declaration of Istanbul. *Lancet* (2008) 372: 5–6.

<sup>5</sup> Report to the Board of Directors, OPTN/UNOS Ad Hoc International Relations Committee, June 28, 2011.

<sup>6</sup> Glazier, A., et al. “Organ transplantation for nonresidents of the United States: A policy for transparency”, *American Journal of Transplantation* (2014): 14; 1740-1743.

<sup>7</sup> 2019 Summary of Non-US Resident Transplant Activity, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

<sup>8</sup> *Proposed Revisions to and Reorganization of Policy 6.0*, OPTN Ad Hoc International Relations Committee & OPTN Ethics Committee, 2011.

<sup>9</sup> UNet<sup>SM</sup> Help Documentation, as of June 2021.

- **Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Transplant:** A non-citizen of the United States for whom the United States is not the primary place of residence, and who came to the U.S. for the purpose of transplant.

**Table 1: Citizenship Status Data Element Changes**

Prior to 2011	Current
Citizenship status data field categories on the TCR & LDR forms: <ul style="list-style-type: none"> <li>• U.S. Citizen</li> <li>• Resident Alien</li> <li>• Non-Resident Alien, Year of Entry to the U.S.</li> </ul>	Citizenship status data field categories on the TCR & LDR forms: <ul style="list-style-type: none"> <li>• U.S. Citizen</li> <li>• Non-U.S. Citizen/U.S. Resident</li> <li>• Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Reason Other than Transplant</li> <li>• Non-U.S. Citizen/Non-U.S. Resident, Traveled to U.S. for Transplant</li> </ul>
Citizenship status data field categories on the DDR form: <ul style="list-style-type: none"> <li>• U.S. Citizen</li> <li>• Resident Alien</li> <li>• Non-Resident Alien, Specify Home Country</li> </ul>	Citizenship status data field categories on the DDR form: <ul style="list-style-type: none"> <li>• U.S. Citizen</li> <li>• Non-U.S. Citizen/U.S. Resident</li> <li>• Non-U.S. Citizen/Non-U.S. Resident</li> </ul>

The Committee utilizes data from the citizenship status data element for their annual report which analyzes activities related to the transplantation of non-U.S. citizen/non-U.S. residents, per *OPTN Policy 17.1.C*. Historically, the Committee also utilized this data to identify transplant programs who reported more than 5% of their deceased donor transplants recipients were non-U.S. citizens. The OPTN removed this provision from policy, often referred to as the “5% Rule”, because it was widely misunderstood as a 5% cap on a transplant program’s ability to list and transplant non-U.S. citizens. Currently, per *OPTN Policy 17.1.B: Review of Non-U.S. Citizens/Non-U.S. Resident Registrations and Transplants*, the Committee may request transplant programs to provide additional information regarding registrations or transplant of NCNR patients.<sup>10</sup>

Given the Committee’s charge, the Committee sought to better understand transplant activity in the U.S. by analyzing citizenship status data. During the summer of 2020, the Committee developed and sent a Program Information Request to 75 transplant programs. The purpose of the Program Information Request was to better understand transplant programs’ policies and practices regarding acceptance of NCNR as transplant patients. The Committee sent their Program Information Request to heart, liver, and kidney programs who met both of the following conditions during any single year from 2017-2019:

- Greater than 5% NCNR registrations or deceased donor transplants for a specific organ
- Greater than 5 NCNR registrations or deceased donor transplants for a specific organ

The Program Information Request had a 44% response rate. 48% of programs that responded indicated their program does not have a formal process for accepting NCNR candidates. 32 of the 33 programs

<sup>10</sup> OPTN Policy 17.1.B, *Review of Non-U.S. Citizens/Non-U.S. Resident Registrations and Transplants* (June 2021).

indicated that their program evaluates the resources available to support NCNR candidates. Programs also provided responses on the documents or processes utilized to establish a NCNR candidate. 20 programs cited the patient (i.e. self-reporting) as the process used to establish a NCNR candidate, while other responses were evenly spread across utilization of passports, referring physicians, family, or government issued evidence.

The Program Information Request results indicated the majority of programs did not know whether their NCNR candidates' country of origin had a transplant program for the organ needed, and did not know whether their NCNR candidates had sought transplant services in their country of origin. While 66% of programs reported having processes to ensure pre-transplant and post-transplant follow-up care, for NCNR patients, literature reported a 10-20 % lower rate of follow-up data submission for living donor NCNR liver and kidney recipients compared to U.S. citizen living donor liver and kidney recipients starting at one-year follow-up reporting.<sup>11</sup> Additional literature reported similar trends for follow-up data submission of deceased donor NCNR liver and heart recipients.<sup>12</sup>

The Committee also reviewed literature related to living donors, as there are living donors from outside of the U.S. who donate organs within the U.S. One peer-reviewed article, which analyzed a cohort of living kidney donors from 2000-2016, showed follow-up rates for NCNR living kidney donors were lower compared to U.S. citizen living kidney donors. U.S. citizen living kidney donor follow-up rates varied between about 65% - 75% for six-month, twelve-month, and twenty-four-month follow-up. In contrast, NCNR living kidney donor follow-up rates varied between about 30% – 45% for six-month, twelve-month, and twenty-four-month follow-up.<sup>13</sup>

In addition to the results from the Program Information Request, as well as review of current literature and data, the Committee reviewed member questions. A few transplant programs requested clarification on how to accurately enter citizenship status. One specific member question that the Committee reviewed stated that they had been inaccurately capturing citizenship status and requested guidance on categorizing patients as NCNR in order to submit better quality data.<sup>14</sup> The Committee concluded that it would be beneficial to further guide the transplant community on the required citizenship status data submitted to OPTN.

The Committee discussed the possibility of a data collection project; however, it was decided that the citizenship status data element, as well as data definitions were acceptable. The Committee moved forward with developing a guidance document by outlining the following goals for the guidance document:

- Accurate data collection
- Adherence to data collection
- Awareness of citizenship status data element
- Share best practices for accurate, complete, and timely data collection

Additionally, during the development of the guidance document, the Committee sought feedback from the OPTN Data Advisory, Minority Affairs, and Transplant Administrators Committees. The Committee received positive support from OPTN collaborating committees. Feedback reinforced the Committee's

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<sup>11</sup> OPTN data from January 1, 2016 – December 31, 2019.

<sup>12</sup> OPTN data as of January 22, 2021.

<sup>13</sup> Ammary, F., et al. "The landscape of international living kidney donation in the United States", *American Journal of Transplant*, (2019) 19(7): 2009-2019.

<sup>14</sup> September 8, 2020 meeting summary, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

decision to address how the citizenship status data element is utilized in order to gain patient trust, as well as address the importance of collecting citizenship status data on deceased donors.

Through feedback from the community and member questions, the Committee found the transplant community had a lack of clarity on the OPTN citizenship status data element, which is collected on the TCR, LDR, and DDR forms. The Committee decided to develop a document to provide the transplant community guidance on the classification of citizenship status. The guidance document addresses accurate capture of citizenship status at registration, as well as the accurate, complete, and timely collection of follow-up data. The guidance document addresses how citizenship status data is utilized with the aim of creating trust and transparency between patients and providers in order to increase the accuracy of reported data.

Accurately capturing the citizenship status of transplant candidates, living donors, and deceased donors is important for the overall integrity and quality of OPTN data. Accurate capture of data allows for analyses to be performed in order to identify and review current trends, and subsequently develop evidence-based policy, if needed. The collection of the citizenship status data element aligns with the OPTN Principles of Data Collection: specifically the data element fulfills the principle of developing transplant, donation, and allocation policies.<sup>15</sup>

Additionally, it is critical for transplant centers to consider the obstacles of accurate, complete, and timely follow-up data submission, given a patient's citizenship status, during the evaluation process. Due consideration of follow-up data submission related obstacles allows programs to take the necessary measures to ensure accurate reporting and OPTN record maintenance as well as ensure stewardship of organs, regardless of citizenship status. Accurate collection of citizenship status allows health care professionals to appropriately plan, with the intent of improving rates of follow-up data submission. Lastly, the guidance document highlights the importance of collecting citizenship status for deceased donors on the DDR.

## Recommendations

The Committee submits the proposed document to provide guidance to transplant programs and OPOs on accurately capturing the citizenship status data element. Per *OPTN Policy 18.1: Data Submission Requirements*, members must report accurate data to the OPTN.<sup>16</sup> The guidance document addresses the purpose of collecting the citizenship status of transplant candidates, living donors, and deceased donors as well as how this data is utilized. The document provides guidance on how to accurately categorize individuals as U.S. citizen, non-U.S. citizen/U.S. resident (NCR), NCNR traveling to U.S. for transplant, and NCNR traveling to U.S. for reason other than transplant, on the OPTN data collection forms. The document provides guidance for how health care professionals can appropriately plan for accurate, complete, and timely follow-up data submission of the Transplant Recipient Follow-up (TRF) and Living Donor Follow-up (LDF) forms, given a patient's citizenship status.

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<sup>15</sup> "Principles of Data Collection," OPTN (June 2021). Available at <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>.

<sup>16</sup> OPTN Policy 18.1, *Data Submission Requirements* (June 2021).

## Transplant Candidate Registration & Living Donor Registration Forms

The TCR and LDR forms are data collection tools which capture citizenship status at time of registering transplant candidates and living donors. The TCR must be submitted by the transplant hospital 30 days after the transplant hospital registers the candidate on the waiting list<sup>17</sup>, and the LDR must be submitted by the recovery hospital 60 days after submission of the living donor feedback form, as outlined in *OPTN Policy 18.1: Data Submission Requirements*.<sup>18</sup>

Data collected from the citizenship status field is neither used for punitive measures against programs nor for determining patient access to transplant. *OPTN Policy 5.4.A: Nondiscrimination in Organ Allocation* states “a candidate’s citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation.”<sup>19</sup> It is important to establish trust and transparency between patients and providers to improve the ability to collect accurate data. It is emphasized that citizenship status data collection lends to fulfilling the OPTN’s function to collect quality data in order to produce evidence-based policy solutions. The guidance document clarifies citizenship status data definitions, and addresses measures that healthcare professionals can use to confirm patient citizenship status and enter accurate related data.

## Transplant Recipient Follow-up & Living Donor Follow-up Forms

The TRF and LDF forms are data collection tools which are utilized to collect post-transplant and post-donation data on recipients and living donors. *OPTN Policy 18.1: Data Submission Requirements*, requires transplant programs to submit organ specific TRF forms 30 days after the six-month and annual anniversary of the transplant date until the recipient’s death or graft failure.<sup>20, 21</sup> However, even with a policy requirement, data shows that deceased donor liver NCNR transplant recipients have lower rates of follow-up compared to deceased donor liver U.S. citizen transplant recipients.<sup>22</sup> Additionally, *OPTN Policy 18.1: Data Submission Requirements* states that recovery hospitals must submit LDF forms 60 days after the six-month, one-year, and two-year anniversary of the donation date.<sup>23, 24</sup> While required follow-up for living donors is a significantly shorter timeframe, the rates of follow-up between U.S. citizens and NCNR patients show similar trends as deceased donor transplant recipients.<sup>25</sup>

The guidance document is a tool for programs with NCNR and NCR transplant recipients as well as NCNR and NCR living donors, to inform themselves on the importance of accurate, complete, and timely patient follow-up data submission planning given a patient’s citizenship status. Some obstacles that health care professionals should consider for NCNR patients are similar to those faced by U.S. citizens, such as the recipient’s access to health insurance and financial resources. Others may differ from the obstacles faced by U.S. citizens, including the following: (1) availability of clinical transplant expertise in

<sup>17</sup> OPTN Policy 18.1

<sup>18</sup> OPTN Data Advisory Committee’s OPTN Board of Directors-approved proposal, *Modify Data Submission Policies*, change this requirement to 90 days following implementation of policy changes. Available at <https://optn.transplant.hrsa.gov/media/3459/modify-data-submission-policies-policy-notice.pdf>.

<sup>19</sup> OPTN Policy 5.4.A, *Nondiscrimination in Organ Allocation* (June 2021).

<sup>20</sup> OPTN Policy 18.1

<sup>21</sup> *Modify Data Submission Policies*, change this requirement to 90 days following implementation of policy changes.

<sup>22</sup> OPTN data as of January 22, 2021.

<sup>23</sup> OPTN Policy 18.1

<sup>24</sup> *Modify Data Submission Policies*, change this requirement to 90 days following implementation of policy changes.

<sup>25</sup> Ammary, F., et al. “The landscape of international living kidney donation in the United States”, *American Journal of Transplant*, (2019) 19(7): 2009-2019.

the NCNR recipient's country of origin or, (2) geographic distance, especially if the recipient returns to their country of origin to receive care.

## Deceased Donor Registration Form

The DDR form is a data collection tool which host organ procurement organizations (OPOs) must submit 30 days after the donor organ disposition feedback form is submitted and disposition is reported for all organs, per *OPTN Policy 18.1: Data Submission Requirements*.<sup>26,27</sup> It is equally important to capture citizenship status for transplant candidates, living donors, and deceased donors. Data collected on deceased donors lends to the ability to contextualize, relevant to the overall population of organ donors and overall population of transplant recipients, the transplantation of NCNR and NCR candidates in the U.S. Additionally, individuals who may be categorized as NCNR or NCR and are in the U.S. at the time of their death, do contribute to the deceased donor organ pool.

## NOTA and Final Rule Analysis

The Committee submits the following proposal under the authority of the National Organ Transplant Act (NOTA), which states the OPTN shall "provide information to physicians and other health professionals regarding organ donation"<sup>28</sup>, as well as the OPTN Final Rule, which states "An organ procurement organization or transplant hospital shall...submit to the OPTN...information regarding transplant candidates, transplant recipients, [and] donors of organs..."<sup>29</sup> and that the OPTN shall:

- (i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
- (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;
- (iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and
- (iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.<sup>30</sup>

The Committee's citizenship status guidance document aims to improve quality of data collection of the existing citizenship status field on the TCR, LDR, and DDR forms by providing information to physicians and OPO professionals about how to appropriately report citizenship status for donors and candidates. The guidance document aims to promote an increase in reported follow-up among NCNR and NCR recipients and donors, given their citizenship status, for OPTN records.

<sup>26</sup> OPTN Policy 18.1

<sup>27</sup> *Modify Data Submission Policies*, change this requirement to 60 days following implementation of policy changes.

<sup>28</sup> 42 U.S.C. §274(b)(2)(H).

<sup>29</sup> 42 CFR §121.11(b)(2).

<sup>30</sup> 42 CFR §121.11(a)(1)(i)-(iv).

## Conclusion

The proposed document provides guidance on the classification of citizenship status as an OPTN data element, and provide information on how the citizenship status data element is utilized. The guidance document addresses accurate collection of citizenship status at registration, and accurate, complete, and timely follow-up data collection given a patient's citizenship status. Accurate collection of citizenship status assists the ability to (1) perform quality data analyses; (2) develop evidence based policies; (3) monitor patient safety and welfare; and (4) ensure stewardship of donated organs.

## Guidance Document

# Guidance for Data Collection Regarding Classification of Citizenship Status

### Introduction

Throughout this document the term ‘citizenship status’ refers to the OPTN data collection element “citizenship status”. This OPTN data element collects information on citizenship, residency, and country of origin. It is not within the OPTN’s function to discern legality of immigration status of patients. Therefore, statements and guidance within this document focus solely on accurately collecting citizenship status as it pertains to OPTN data collection.

This guidance document may be used as a resource for transplant programs and organ procurement organizations (OPOs) to reference to ensure accurate collection of the OPTN citizenship status data element. The OPTN collects quality data on transplant candidates, organ donors, and transplant recipients<sup>31</sup>, which are used for various purposes, including developing evidence-based policies and ensuring that the OPTN can provide information to physicians and other health professionals regarding organ donation.<sup>32</sup>

In 2018, non-U.S. citizens/non-U.S. residents comprised 1.3% of transplant candidate registrations, and 1.4% of organ recipients.<sup>33</sup> *OPTN Policy 5.4.A: Nondiscrimination in Organ Allocation states, “a candidate’s citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation. Allocation of deceased donor organs must not be influenced positively or negatively by political influence, national origin, ethnicity, sex, religion, or financial status.”*<sup>34</sup>

OPTN data designates non-U.S. citizens into two distinct categories:

- Non-U.S. citizen/non-U.S. resident
- Non-U.S. citizen/U.S. resident

OPTN Policy defines non-U.S. citizen/non-U.S. residents as, “a non-citizen of the United States for whom the United States is not the primary place of residence.”<sup>35</sup> A non-U.S. citizen/U.S. resident is defined in OPTN Policy as “a non-citizen of the United States for whom the United States is the primary place of residence.”<sup>36</sup>

OPTN data collection for citizenship status does not address the legal status of an individual’s place of residency. Primary place of residency is solely intended to capture where an individual lives, regardless of their legal status. It is not within the scope of the OPTN’s function to discern transplant candidates, living donors, and deceased donors’ legal citizenship status, therefore, it is not a factor when collecting citizenship status data.

<sup>31</sup> 42 C.F.R. §121.11(a)(1)(i)-(iv); 42 C.F.R §121.11 (b)(2).

<sup>32</sup> 42 U.S.C. §274(b)(2)(H).

<sup>33</sup> 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee. Available at <https://optn.transplant.hrsa.gov/>.

<sup>34</sup> OPTN Policy 5.4.A, *Nondiscrimination in Organ Allocation* (June 2021).

<sup>35</sup> OPTN Policy 1.2, *Definitions* (June 2021).

<sup>36</sup> OPTN Policy 1.2

38  
 39 There are many direct and indirect benefits to ascertaining the citizenship status of both organ donors  
 40 and organ recipients. For instance, accurate tracking of citizenship status helps determine the non-U.S.  
 41 citizens/non-U.S. resident's deceased organ donor to organ recipient ratio. As organ transplantation is a  
 42 cost-efficient way of managing end-stage organ failure, ascertaining the citizenship status can help shed  
 43 some light on the net healthcare cost of the non-U.S. citizens/non-U.S. residents' and non-U.S.  
 44 citizens/U.S. residents' beneficiaries. Additionally, the citizenship status data element is the sole data  
 45 element that allows the OPTN to review citizenship, residency, and country of origin of its patient and  
 46 donor population.

47  
 48 The concern for ascertaining the citizenship status among organ donors and organ recipients has been  
 49 explored in the past. In 2012, the terminology of citizenship status reporting was changed to replace  
 50 "resident alien" and "non-resident alien", with "non-U.S. citizen/U.S. resident", "non-U.S. citizen/non-  
 51 U.S. resident who traveled to the U.S. for transplant", and "non-U.S. citizen/non-U.S. resident who  
 52 traveled to the U.S. for reason other than transplant".<sup>37</sup> The basis for this change was to properly  
 53 analyze transplant tourism, as outlined in the *Declaration of Istanbul*, within the U.S.<sup>38</sup>

54  
 55 Ascertaining citizenship status can be a complex task. Some of the complexities may be related to the  
 56 inexperience of the transplant professional asking the questions, language barriers, or fear of  
 57 immigration-related punitive consequences, especially in regions of the U.S. that do not routinely  
 58 accommodate undocumented immigrants. Finally, the lack of policies to guide transplant programs and  
 59 OPOs reporting the documentation status further complicate the matter.

## 61 **Registration Data Collection**

62 The current categorization scheme of the citizenship status data element on the Transplant Candidate  
 63 Registration (TCR), Living Donor Registration (LDR), Deceased Donor Registration (DDR) forms allow the  
 64 OPTN to better capture all activities pertaining to transplantation of non-U.S. citizen/U.S. resident and  
 65 non-U.S. citizen/non-U.S. resident. Citizenship status information is provided by the transplant program  
 66 and OPO staff filling out the data collection forms in UNet<sup>SM</sup> at the time of listing transplant candidates,  
 67 living donors, and deceased donors. U.S. transplant programs and OPOs should ensure accurate  
 68 information is provided by the transplant candidate, organ donor, or their care giver. There are several  
 69 factors that contribute to inaccurate collection of citizenship status at registration. Four main factors are  
 70 outlined below, as well as guidance on how to improve accurate collection of the citizenship status data  
 71 element.

### 72 73 **1. Clarity on citizenship status definitions of donors and recipients**

74 Various interpretations of the citizenship status data elements have resulted in misclassification of  
 75 citizenship status for patients. The following categories of citizenship status are the current data  
 76 element choices collected on the TCR and LDR forms:

- 77 I. U.S. citizen
- 78 II. Non-U.S. citizen/U.S. resident
- 79 III. Non-U.S. citizen/Non-U.S. resident, who traveled to U.S. for reason other than transplant

<sup>37</sup> *Proposed Revisions to and Reorganization of Policy 6.0*, OPTN Ad Hoc International Relations Committee & OPTN Ethics Committee, 2011.

<sup>38</sup> Steering Committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism: The Declaration of Istanbul. *Lancet* (2008) 372: 5–6.

80 IV. Non-U.S. citizen/Non-U.S. resident, who traveled to U.S. for transplant.

81

82 The first data element for the citizenship status data collection, U.S. citizen, is defined in the UNet Help  
83 Documentation<sup>39</sup> as, “a United States citizen by birth or naturalization.” Any transplant candidate or  
84 organ donor who was born in the United States, or has completed the United States naturalization  
85 process is to be categorized as U.S. citizen.

86

87 Non-U.S. citizen/U.S. resident is defined in the UNet Help Documentation<sup>40</sup> as, “a non-citizen of the  
88 United States for whom the United States is the primary place of residence.” To categorize a transplant  
89 candidate or organ donor as non-U.S. citizen/U.S. resident, the patient must be living in the U.S.  
90 Whether or not the patient has documentation or authorization to be a resident of the U.S. is not a  
91 factor.

92

93 Non-U.S. citizen/non-U.S. resident, who traveled to U.S. for reason other than transplant, is different  
94 than the previously mentioned data element, because categorization requires the transplant candidate  
95 or organ donor to be traveling in the U.S., not residing. This data element is defined in the UNet Help  
96 Documentation<sup>41</sup> as “a non-citizen of the United States for whom the United States is not the primary  
97 place of residence, and who came to the U.S. for a reason other than transplant.” A common reason for  
98 traveling to the U.S. for a reason other than transplant are vacation, visiting relatives/friends, business,  
99 and temporary student.

100

101 A transplant candidate or organ donor whose sole purpose of being in the United States is organ  
102 transplantation is to be categorized as non-U.S. citizen/non-U.S. resident, who traveled to U.S. for  
103 transplant. This data element is defined in UNet Help Documentation<sup>42</sup> as, “a non-citizen of the United  
104 States for whom the United States is not the primary place of residence, and who came to the U.S. for  
105 the purpose of transplant”.

106

107 For any patient who is not a U.S. citizen and is not a resident in the U.S., a transplant program or OPO  
108 should obtain the country of origin and date of entry into the U.S.

109

## 110 **2. Various data sources used by transplant programs and OPOs**

111 Transplant programs and OPOs are using inconsistent processes and/or documents to determine the  
112 citizenship status of candidates and organ donors. Since most residency and citizenship statuses are self-  
113 reported by patients, family, and referring physicians, information regarding citizenship, primary place  
114 of residency, country of origin, and year of entry into U.S. most likely cannot be validated. The additional  
115 determination of traveling to the U.S. for reasons other than transplant versus traveling for transplant is  
116 also determined by transplant programs, who may have different interpretations for these various  
117 classifications.

118

119 Use of data from non-validated sources may lead to incorrect data reporting on donors and recipients in  
120 UNet at the time of listing transplant candidates and organ donors. Transplant program and OPO staff

<sup>39</sup> UNet<sup>SM</sup> Help Documentation, as of June 2021.

<sup>40</sup> UNet Help Documentation, as of June 2021.

<sup>41</sup> UNet Help Documentation, as of June 2021.

<sup>42</sup> UNet Help Documentation, as of June 2021.

121 may not be formally educated on verification of residency status.<sup>43</sup> Transplant programs should  
 122 consider, and implement, a set standard for the types of source documentation utilized when reporting  
 123 citizenship status.

124

### 125 **3. Challenges to the language barriers and legal status**

126 Non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident patients may come from non-  
 127 English speaking countries, or English as their second language.<sup>44</sup> Low English proficiency puts patients  
 128 at the greatest challenges in communicating with transplant staff, which may result in inaccurate data  
 129 collection.

130

131 Additionally, undocumented patients may have fears about being rejected from being able to receive an  
 132 organ transplant or their families may fear potential repercussions of immigration enforcement if they  
 133 consent to donate a patient's organs and identify as non-U.S. citizens/non-U.S. residents, or non-U.S.  
 134 citizen/U.S. resident.

135

136 Transplant programs should provide medical or credentialed interpreters skilled at acquiring the  
 137 information needed and alleviating the fears of the patient and the family consenting for donation.  
 138 Transplant program staff should explain that the transplant system does not exclude patients on the  
 139 basis of citizenship, residency, or immigration status. Per *OPTN Policy 5.4.A: Nondiscrimination in Organ  
 140 Allocation* states "a candidate's citizenship or residency status in the United States must not be  
 141 considered when allocating deceased donor organs to candidates for transplantation."<sup>45</sup> Transplant  
 142 program staff should explain to patients that citizenship status data is utilized for transparency and the  
 143 ability to perform quality data analyses in order to create evidence based policy which ensures patient  
 144 safety and welfare. Addressing language barriers and informing patients on how OPTN citizenship status  
 145 data is utilized aims to create trust between patients and providers, thus improving the accuracy of  
 146 reported citizenship status for data collection.

147

### 148 **4. Processes for ensuring accurate citizenship status data collection**

149 *OPTN Policy 18.1: Data Submission Requirements* states that members must report accurate data to the  
 150 OPTN<sup>46</sup>. Transplant programs and OPOs would more consistently and accurately meet these  
 151 requirements with established, documented approaches to data collection in place.

152

### 153 **Follow-up Data Collection**

154 OPTN policy requires transplant programs to submit Transplant Recipient Follow-up (TRF) and Living  
 155 Donor Follow-up (LDF) forms. The follow-up data collection rates for non-U.S. citizen/non-U.S. residents  
 156 and non-U.S. citizen/U.S. residents are significantly lower than follow-up data collection rates for U.S.  
 157 citizens.<sup>47</sup> Non-U.S. citizen/non-U.S. resident and non-U.S. citizen/U.S. resident recipient and donor loss  
 158 to follow up and non-adherence may due to the following reasons:

159

1. Recipient/donor is uninsured or is afraid of financial burden

<sup>43</sup> Delmonico FL, et al. Deceased Donor Organ Transplantation Performed in the United States for Noncitizens and Nonresidents. *Transplantation*. 2018;102(7):1124-1131.

<sup>44</sup> 2019 Annual Report of Non-U.S. Resident Transplant Activity, OPTN Ad Hoc International Relations Committee.

<sup>45</sup> OPTN Policy 5.4.A

<sup>46</sup> OPTN Policy 18.1, *Data Submission Requirements* (June 2021).

<sup>47</sup> Ammary, F., et al. "The landscape of international living kidney donation in the United States", *American Journal of Transplant*, (2019) 19(7): 2009-2019.

- 160 2. Undocumented immigration status that prevents recipient/donor from getting a non-
- 161 emergency health insurance
- 162 3. Costs for travel, in the event there is no follow-up in the country of origin, especially seen in
- 163 the international and out of state long distance recipient/donors
- 164 4. Lack of support and resources
- 165 5. Lack of job security or is unable to take time off for the clinic visit
- 166 6. Recipient/donor's demographic such as age, gender, ethnicity
- 167 7. Physically feeling well and no clear substantial medical reasons for follow up

168  
 169 Before a transplant program engages in transplant activity with non-U.S. citizens/non-U.S. residents and  
 170 non-U.S. citizens/U.S. residents, it is critical for the transplant program to consider its ability to collect  
 171 follow-up data on patients. Development of recipient and living donor follow up protocols may ensure  
 172 the long-term health of donors, ensure stewardship of organs, and improve the quality of follow-up data  
 173 submissions.<sup>48</sup> The following are suggestions for improving rates of follow-up data submission for non-  
 174 U.S. citizen/U.S resident and non-U.S. citizen/U.S. resident recipients and donors:

- 175 1. Inform recipient/donors from the very first contact that follow-up is critical
- 176 2. Inform recipients/donors during clinic so information can be collected for TRF/LDF data
- 177 collection
- 178 3. Develop strong staff commitment to ensure there is adherence to recipient/donor follow-up
- 179 4. Relationship building by using a dedicated living donor coordinator or social worker
- 180 5. Schedule donor and recipient follow up at the same clinic visit
- 181 6. Inform recipient/donors from the very first contact that follow-up is critical
- 182 7. Increase recipient/donors' own commitment to a healthy lifestyle post-donation
- 183 8. Ask recipients/donors to establish a relationship with a primary care physician close to their
- 184 home of residence
- 185 9. If recipient/donor will be visiting the primary care physician rather than the transplant
- 186 center for LDF data collection, send a letter for primary care physician
- 187 10. Develop a systematic approach to follow-up with quality assurance

188  
 189 This guidance is provided to the OPTN Board of Directors in order to assist the transplant community in  
 190 accurately capturing citizenship status at time of registration, and address accurate, complete, and  
 191 timely submission of follow-up data.

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<sup>48</sup> Lentine, K., et al. Care of International Living Kidney Donor Candidates in the United States. *The Journal of Clinical and Translational Research*.