[Date]

Dear [Transplant Candidate],

You are receiving this letter because you are registered on our waiting list for a [organ type] transplant at [Transplant Center]. We are writing to inform you of an important UNOS (United Network for Organ Sharing) policy change that will affect the waiting time for some candidates on our waiting list.

Waiting time is important and is a major factor in identifying who receives offers for available deceased donor kidneys. A longer waiting time may increase your chances of receiving an organ offer. Waiting time is based on the earliest date of your eGFR (glomerular filtration rate) less than or equal to 20 mL/min. (on or after registration on the waiting list) or the date you began regularly administered dialysis as an End Stage Renal Disease patient. Your eGFR rate measures how well your kidneys are working; an eGFR of 20 or below means you have a severe loss of kidney function. Research shows that Black or African American patients have historically been disadvantaged by the use of eGFR formulas that included race as a factor in the calculation.

On January 5, 2023, a UNOS Policy was put into effect that requires all transplant programs to do the following by January 3, 2024:

- 1. Communicate this policy change to ALL candidates on our kidney transplant waiting list;
- 2. Review their waiting lists to see if any Black or African American candidates may be eligible to receive additional waiting time based on a previously used eGFR formula that included race as a factor in the calculation;
- 3. Submit a request for additional waiting time for candidates that may be eligible and have supporting documentation;
- 4. Inform ALL candidates of their eligibility for additional waiting time.

Although [Transplant Center] adopted the use of race neutral GFR calculators in 2021, when it was recommended by a Task Force of the American Society of Nephrology, it is possible that Black or African American candidates were referred and listed utilizing a race inclusive calculation prior to this practice change.

Based on our records, your race **HAS BEEN** identified as Black or African American. **This means that you may be eligible for an adjustment to your waiting time under this policy.** In order to submit a request for waiting time modification, we need evidence (a lab report) with both creatinine and a race inclusive eGFR value of *over 20* that is recalculated as *20 or less* when using a race-neutral equation. We will be working closely with your referring provider and/or dialysis center to review all of your available medical records for this.

Please see the enclosed "FAQs." If you have questions, concerns or would like further information on this policy change, please contact the UNOS Patient Services Line (toll free) at 1-888-894-6361 or you can visit: https://optn.transplant.hrsa.gov/patients/by-organ/kidney/understanding-the-proposal-to-require-race-neutral-egfr-calculations/

And as always, feel free to contact us with any questions. You can reach your Transplant Coordinator via [contact information]. When calling, please state that you need to speak with Waitlist Transplant Coordinator regarding the waiting time adjustment for Black or African American candidates. We try to

return all non-urgent calls within 3 business days but ask that you please be patient if there is any delay in getting back to you.

Sincerely,

Your [Transplant Center] Kidney Transplant Team

FAQs: Understanding race & eGFR

What is eGFR?

The estimated glomerular filtration rate, or eGFR for short, measures how slowly or quickly kidneys remove a waste product called creatinine from the blood. This calculation helps doctors understand how sick a kidney patient is. There are actually a number of different eGFR calculations, and they don't all use the same factors. Different transplant hospitals can use different eGFR formulas when they try to determine how sick their patients are.

Did the OPTN develop eGFR calculations?

No, the OPTN did not develop any of the eGFR calculations currently used, but eGFR values are used throughout <u>OPTN transplant policy</u>. For example, a kidney candidate's eGFR is used as one of several ways to determine when the patient is able to start adding waiting time on the transplant waiting list. More details about what OPTN policy says about eGFR can be found below.

What is the Black race variable in eGFR?

A variable is part of a formula. One of the most widely used formulas for measuring eGFR includes a Black race variable. This formula is the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). There are additional formulas that also use a Black race variable.

The CKD-EPI formula can use as many as four patient-specific variables:

- Creatinine clearance (how quickly your kidneys can filter waste products from your blood)
- Age
- Gender
- Race (when race is used as a variable, patients are categorized as Black or Not Black)

The Black race variable was established from study results, which showed that Black patients had higher levels of creatinine. In order to adjust for these assumed differences, some eGFR formulas include a Black race variable that automatically increases all Black patients' eGFR values.

Do all eGFR formulas use a Black race variable?

No, not every eGFR formula uses a Black race variable. There are a number of different eGFR calculations, and they don't all use the same factors. Different transplant hospitals can use different eGFR formulas. Hospitals are required to use eGFR formulas without a Black race variable, effective July 27, 2022.

What does using a race variable mean for patients?

Recent research^[2] suggests that using a Black race variable in eGFR could actually disadvantage Black patients with chronic kidney disease. For example, studies suggest that using the variable in the CKD-EPI formula has the potential to overestimate Black patients' kidney function by as much as 16 percent. Some researchers and clinicians also question the design of the original studies that led to the development of the Black race variable^[3].

Why is it a problem to overestimate a patient's kidney function?

It's a problem to overestimate a patient's kidney function because it means they could appear to be less sick on paper than they actually are. This especially matters in relation to when candidates start to get waiting time. For adult candidates who are not on dialysis, eGFR values must be less than or equal to 20 mL/min to start waiting time.

Patients with overestimated eGFRs may take longer to access waiting time on the transplant waiting list. The overestimation of Black patients' eGFRs could also lead to poor management of chronic kidney disease, as well as overall worse outcomes for those patients^[4]. Read the committees' co-sponsored <u>proposal</u> for more information.

In this broad example (which uses the CKD-EPI equation), Candidate A is categorized as Black and Candidate B is categorized as not-Black. They are identical for all patient-specific variables except for race.

Factors	Candidate A	Candidate B
Sex:	Male	Male
Age (years):	60	60
Black Race:	Yes	No

Factors	Candidate A	Candidate B
Serum Creatinine (mg/dL):	3.3	3.3
eGFR (<i>mL/min/1.73m</i> ²)::	23.3	19.2

As a result of the Black race variable in the example shown here, the not-Black Candidate B's eGFR is 19.2, so he would qualify to start to get waiting time.

Because the Black Candidate A's eGFR is above 20, he would not start to get waiting time, and his eGFR might have been overestimated.

What does OPTN policy say about eGFR?

GFR values are used as qualifying thresholds for adult kidney candidates throughout OPTN policy. Most notably, eGFR is used as a qualifier for beginning waiting time on the kidney transplant list. Under the previous policy, there were no specifications as to which calculations should or should not be used to meet eGFR qualifying thresholds in OPTN policy. The changes to policy approved on June 27, 2022, require use of a race-neutral calculation, effective July 27, 2022.

How is eGFR used as a qualifying threshold for waiting time?

Patients older than 18 years old have to meet one of the following three requirements before they can start to get waiting time:

- They receive regularly administered dialysis for end-stage renal disease (ESRD)
- They have an eGFR of less than or equal to 20 mL/min
- They have a creatinine clearance of less than or equal to 20 mL/min

Does my eGFR prevent me from being listed as a candidate for transplant?

No. OPTN policy states that a kidney transplant candidate may be registered to the transplant waiting list **with any eGFR.** However, no candidate will start waiting time until they meet **one of the above** qualifications. Some transplant hospitals may have their own protocols for referral, so be sure to ask your transplant hospital when you can be registered to the transplant waiting list.

Why is this important in terms of equity?

The use of eGFR as a threshold for starting to get waiting time is important, because it can impact how much waiting time a kidney patient accrues. The amount of waiting time a kidney patient has accrued is critical - it plays a big role in the prioritization of kidney offers. If the Black race variable was used to calculate a patient's eGFR, they may have to wait longer to reach the threshold to get waiting time. This would disadvantage Black patients trying to access transplant.

What else should I know about the race variable in eGFR?

GFR calculators with race variables only offer two response options: "Black" or "Not Black."

These two options do not allow for mixed race or multi-racial individuals, and do not account for the existing genetic diversity within the Black population.

Did my doctor use the Black race variable to calculate my eGFR?

The answer to this question will depend upon the transplant program where you are registered. Your doctor is the best resource to answer this question. The OPTN does not collect this information.

If you have questions, concerns or would like further information on this policy change, please contact the UNOS Patient Services Line (toll free) at 1-888-894-6361 or you can visit: https://optn.transplant.hrsa.gov/patients/by-organ/kidney/understanding-the-proposal-to-require-race-neutral-egfr-calculations/