



January 2, 2025

HRSA Information Collection Clearance Officer  
Room 14NWH04  
5600 Fishers Lane  
Rockville, MD 20857  
[paperwork@hrsa.gov](mailto:paperwork@hrsa.gov)

**Re: Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915-0157—Revision (the “Information Collection Request”)**

Dear Administrator Carole Johnson:

As President of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to respond to the Information Collection Request referenced above. ASTS is a medical specialty society representing approximately 2,000 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

**The Information Collection Request:**

The above-referenced Information Collection Request authorizes HRSA to add data collection forms for candidates listed in the OPTN organ transplant waiting list to the existing OMB-approved information collection.

In addition, HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**ASTS Response:**

ASTS' comments with respect to the collection of data regarding waitlisted candidates are set forth in our separate comments filed in response to *Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network* published in the *Federal Register* on November 4, 2024.

More generally, we believe that the data collection process should be significantly streamlined and updated. We are aware that a new contractor is likely to be selected to address the OPTN's data collection needs as one component of the OPTN Modernization Initiative and we urge HRSA and its contractor(s) to work with **the OPTN Data Advisory Committee (DAC) to conduct a systematic assessment of how the data collection process could**

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**be streamlined and updated, in advance of implementing necessary changes.**

Inefficiencies in the current system that require repetitive input of demographic and other data should be eliminated, and the process for the review, approval and for the removal of data elements that are no longer needed should be streamlined and modified to take less time.

Our comments regarding the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden were submitted in response to a 2020 Request (HRSA Information Collection Request: Data System for Organ Procurement and Transplantation Network OMB No. 0915-0157-Extension. Document no. 2019-28370) (attached).

Finally, we note that the Information Collection Request was not subject to OPTN public comment processes but rather was made public for the first time in the *Federal Register*. The OPTN generally publishes a comprehensive explanation of proposed policy and data collection changes which facilitates relevant and useful feedback from the transplant community. By contrast, the *Federal Register* process used here is less user-friendly: in fact, the relevant forms and proposed changes to those forms are not linked to the notice and obtaining them requires potential commenters to call or e-mail the agency. **We urge HRSA to refrain from bypassing OPTN public comment procedures**, and to the extent those procedures are bypassed due to emergency circumstances requiring immediate action, **links to all relevant documents should be included** in the *Federal Register* notice.

If you have any questions, please do not hesitate to contact Emily Besser, MA, CAE, Associate Director, Advocacy & Professional Practices, at [Emily.Besser@asts.org](mailto:Emily.Besser@asts.org) with questions.

Respectfully,



Ginny L. Bumgardner, MD, PhD, FACS  
President



*Saving and improving lives with transplantation.*

**American Society of Transplant Surgeons®**

March 2, 2020

Thomas J. Engels, Administrator  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

**Re: HRSA Information Collection Request: Data System for Organ Procurement and Transplantation Network OMB No. 0915-0157-Extension. Document no. 2019-28370**

Dear Administrator Engels:

The American Society of Transplant Surgeons (ASTS) is pleased to have the opportunity to comment on the Health Resources and Services Administration (HRSA) request for public comment regarding the burden estimate of proposed data collection projects of the Paperwork Reduction Act of 1995. ASTS is a medical specialty society representing over 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS strongly supports the collection of pertinent data regarding deceased organ donors, living organ donors, transplant candidates, and recipients of organ transplantation, with the goal of improving care and serving the overall benefit to patients. However, this collection of data must be balanced against the resources necessary for such collection and the opportunity costs it imposes (particularly on clinical personnel). Until data collection can occur automatically through electronic methods, we must carefully determine which data elements are most important and necessary to derive benefits for the patients.

**1. Necessity and utility of the proposed information collection for the proper performance of the agency's functions:**

The ASTS recognizes that a robust, ongoing, clinical data repository is integral to improvements in care, quality assurance, innovation, formulation of appropriate organ allocation policy, and resource allocation. It is also necessary for proper risk stratification and is required to scientifically address vexing problems facing our patients. In fact, additional data elements are necessary to most accurately determine clinically significant risk stratification. It is important to note that clinical transplant data is routinely used by a variety of stakeholders including transplant centers, organ procurement organizations, third party payers, scientists, pharmaceutical companies, device manufacturers, and policy makers.

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## **2. Accuracy of the estimated burden:**

To date, the vast majority of data collection still requires manual abstraction, thus imposing significant burden on organizations required to obtain it. The accuracy of the burden estimate is difficult to validate across histocompatibility labs, organ procurement organizations, and transplant centers. Variation exists in the process of data collection and reporting. It is not uncommon for institutions to utilize employees to abstract data elements directly from the electronic health records (EHR). The qualifications, experience, efficiency, cost, and turnover rates of these employees differ from institution to institution. Many organizations utilize clinically trained personnel for these jobs, most commonly nurses. While this may improve the quality of data collected, it does generate a significant cost differential.

## **3. Ways to enhance the quality, utility, and clarity of the information to be collected:**

We believe that enhancing the quality and utility of data collection can best be achieved by improving the accuracy, completeness, and validity of the data reported. Further refining clinically relevant data elements will also serve to improve risk stratification.

## **4. Use of automated collection techniques or other forms of information technology to minimize the information collection burden:**

Ideally, automated electronic capture, abstraction, reporting, and analyses utilizing machine learning and artificial intelligence will enable much more comprehensive collection of increasingly granular and clinically relevant data. However, most institutions do not have this capability, except perhaps for relatively small subsets of required data, and continue to utilize manual abstraction. Additionally, variation exists in the availability, efficiency, and interoperability of the information systems utilized. We believe the creation of a standardized automated collection system would produce the most effective and efficient means of collecting these data. We recommend HRSA consider engaging Electronic Health Record (EHR) vendors to develop above-mentioned technologies to optimize electronic data capture and transfer.

We appreciate HRSA's request for information on burden assessments. We encourage the agency to carefully assess any potential cost implications and work burden against added value when considering future additions or changes to data collection requirements. Additionally, the ASTS believes Patient Reported Outcomes will also provide unique and important information that is not currently being captured and will supplement or may eventually replace elements of these datasets, and therefore urges HRSA to consider methods to engage patients for this purpose.

We would be pleased to work with HRSA, the OPTN, and SRTR to address these concerns and better serve our patients and the transplant community.

Sincerely yours,



Lloyd E. Ratner, MD, MPH, FACS, FICS(Hon)  
President