

DATE: April 7, 2020
TO: Elizabeth Ashley, OMB Desk Officer
FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

Request: The Health Resources and Services Administration (HRSA) Division of Transplantation requests approval for non-substantive changes to the Stem Cell Therapeutic Outcomes Database Collection (OMB #0915-0310, expires 10/31/2022).

Purpose: The purpose of this request is to make changes to the Pre-Transplant Essential Data (Pre-TED) and Post-Transplant Essential Data forms to collect relevant data related to COVID-19 (SARS-CoV-2) infection. This memo explains the changes and supporting rationale.

The **Pre-Transplant Essential Data (Pre-TED) Form 2400** is being modified to add three additional questions to the form to capture COVID-19 (SARS-CoV-2) infection before transplant. One question will capture if the patient has been infected with COVID-19 (SARS-CoV-2) at any time prior to the start of the preparative regimen. If so, two additional questions have also been added for completion to capture if the patient required hospitalization and if mechanical ventilation was given.

The **Post-Transplant Essential Data F2450** is being modified to capture if the recipient developed COVID-19 (SARS-CoV-2) in the reporting period by adding one question. Additionally, COVID-19 (SARS-CoV-2) has been added as a discrete response option for cause of death.

This information will be used as part of the statutory requirement of the C.W. Bill Young Cell Transplantation Program (CWBYCTP) to collect outcomes data for patients who receive blood stem cell transplants. The information will be critical to understand the impact of COVID-19 to these patients' survival and will be vital for risk adjustments to fulfill the statutory required annual report on transplant center outcomes. These questions will be included in the standardized electronic data collection forms system to ensure sufficient quality of the data received

- Time Sensitivity:** The SCTOD data collection changes must be completed in a timely manner to fulfill CWBYCTP requirements. To collect data on this form by early-May, approval of these changes is needed by April 15, 2020. Incorporating these changes expediently is essential to the quality and completeness of data about COVID-19 infection. The next release for data collection forms is scheduled approximately three months later.
- Burden:** The changes included herein do not substantially change the estimated reporting burden about patients with these indications.

PROPOSED CLARIFICATIONS AND CHANGES FOR STEM CELL THERAPEUTIC OUTCOMES DATABASE FORMS:

Form 2400 – Pre-Transplant Essential Data (Pre-TED)

a. Question 88, page 13 – Addition

New question “Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of the preparative regimen / infusion?”

Rationale: To have the ability to better understand the impact of previous COVID-19 infection on subsequent blood stem cell transplantation.

b. Question 89, page 13 – Addition

New question “Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?”

Rationale: To capture if COVID-19 infection required hospitalization, one measure of the severity of COVID-19 infection.

c. Question 90, page 13 – Addition

New question “Was mechanical ventilation given for COVID-19 (SARS-CoV-2) infection?”

Rationale: To capture if mechanical ventilation was previously given specifically for a recipient with previous COVID-19 infection, another measure of COVID-19 severity.

d. Question 91, page 13 – Change/Addition

Add phrase “(excluding COVID-19 (SARS-CoV-2))” to the question, “Is there a history of mechanical ventilation (excluding COVID-19 (SARS-CoV-2))?”

Rationale: To clarify the existing question on mechanical ventilation excludes recipients who received mechanical ventilation for COVID-19 infection. Question 90 above asks about mechanical ventilation specifically for COVID-19 infection.

Form 2450 Post-Transplant Essential Data

a. Question 3, page 2 – Addition

New option for “COVID-19 (SARS-CoV-2)” as a primary cause of death.

Rationale: Capture COVID-19 as the primary cause of death.

b. Question 5, page 4 – Addition

New option for “COVID-19 (SARS-CoV-2)” as a contributing cause of death.

Rationale: Capture COVID-19 as the contributing cause of death.

c. Question 50, page 12 – Addition

New question “Did the recipient develop COVID-19 (SARS-CoV-2) since the date of last report?”

Rationale: Understand which recipients developed COVID-19 (SARS-CoV-2) infection after receiving a transplant and evaluate the impact of COVID-19 infection on transplant outcomes.

d. Question 51, page 12 – Addition

New question “Date of diagnosis”.

Rationale: Capture date of diagnosis for COVID-19 and allow CIBMTR to capture multiple infection events for the same transplant.

Attachments:

1. Original Form **OMB 095-0310 F2400 R7 (version 10Mar2020)**. Current, approved form.
2. Updated Form **OMB 095-0310 F2400 R7 (version 03Apr2020)**. All texts highlighted in yellow are changes and items highlighted in blue are additions to the attached document.
3. Original Form **OMB 095-0310 F2450 R5 (version 17Oct2019)**. Current, approved form.
4. Updated Form **OMB 095-0310 F2450 R5 (version 03Apr2020)**. All texts highlighted in blue are additions to the attached document.