DATE:

TO: Josh J. Brammer, OMB Desk Officer

FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

---

Request: Non-substantive change request for the OMB clearance package for the Health Resources and Services Administration Healthcare Systems Bureau Stem Cell Therapeutic Outcomes Database Collection (SCTOD) (OMB #0915-0310, expires 10/31/2022)

Purpose: The **Pre-Transplant Essential Data (Pre-TED) Form 2400** is being modified to move questions that capture consent to submit research data to a new "Tool" within the FormsNet3 (FN3) application. Additionally, minor updates were made to align data collection with new data quality and gene therapy initiatives.

The overall scope of change in data collected for the Pre-TED Form 2400 is minimal, representing an update in the data collection process. Two placeholder questions have been added to capture the clincaltrials.gov identification number and gene therapy product name, specifically for gene therapy recipients in the future. The National Marrow Donor Program (NMDP) donor ID has been removed, in compliance with the updated World Marrow Donor Association guidelines, as the Global Registration Identifier for Donors will now be utilized.

Centers will still report consent for patients' research status. Still, as stated, it will be captured on a "Tool" in CIBMTR's web-based data collection platform FN3 to align with an initiative to collect essential patient information earlier in the patient registration process. The CIBMTR observational research database consent is currently captured on the Pre-TED Form 2400, which is frequently completed by centers after the infusion date, preventing CIBMTR from capturing this essential information early enough in the process.

To address the issue above and collect consent at the earliest point possible in FN3, a new tool is being developed to capture consent after a CIBMTR Research ID has been created. The tool will also enable the centers' Clinical Research Professionals to add and update consent(s) at any time without requiring updates to the Pre-TED Form.

Time Sensitivity: The data collection changes must be completed promptly to fulfill program requirements. Because CIBMTR needs to maintain consistency across its data collection forms, these changes also relate to other CIBMTR forms used to support our cellular therapy initiatives. To collect data on this form by mid-January, approval of these changes is needed by December 11th, 2020. The next release for data collection forms is scheduled approximately three months later.

Burden: The proposed revisions do not substantially change the estimated reporting burden about patients with these indications.

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

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

a. **Consent to Submit Research Data– Removed**
   Removed questions 14-16 on F2400 R7, capturing consent to the research database and permission to be directly contacted by CIBMTR, to new consent tool.
   Rationale: To support CIBMTR's efforts to collect recipient consent to the research database earlier in the data collection process, before the start of conditioning.

b. **Question 23 – Addition**
   Added question that captures "clinicaltrials.gov identification number."
   Rationale: This field will be used for gene therapy patients in the future. The question will be disabled until the Spring (April) 2021 Release.

c. **NMDP donor ID – Removed**
   Removed NMDP donor ID (Q60 on F2400 R7).
   Rationale: NMDP / CIBMTR will be utilizing the GRID moving forward.

d. **Questions 82 -83 – Additions**
   Added questions capture the gene therapy "product name."
   Rationale: This field will be used for gene therapy patients in the future. The question will be disabled until the Spring (April) 2021 Release.

Attachments:

1. Pre-Transplant Essential Data F2400 R8. All changes highlighted in yellow are revisions, and changes highlighted in blue are additions to the attached document.