**DATE:** April 8, 2024

**TO:** Daniel Cline, OMB Desk Officer

**FROM:** Joella Roland, 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 (SCTOD) Collection (OMB 0915-0310 expiration date 08/31/2025).

**Purpose**: The purpose of this request is to request a minor revision to the pre-transplant data collection to maintain effective data collection. This memo explains the changes and supporting rationale.

One **pre-transplant variable** will be updated to include the “Transformed to AML” response option that was mistakenly removed during the last request (approved 2/8/2024). This response option was previously approved and is still needed (see Table 1, Item ID PRE245).

**Time Sensitivity**: The SCTOD data collection changes must be completed in a timely manner to fulfill C.W. Bill Young Cell Transplantation Program requirements. This nominal change is considered non-substantive and is scheduled for release in April 2024.

**Burden:** The change requested is non-substantive and does not change the estimated reporting burden.

**SUMMARY OF PROPOSED NON-SUBSTANTIVE CHANGES FOR STEM CELL THERAPEUTIC OUTCOMES DATABASE VARIBLES.**

**Details can be found in Attachment 1 (complete spreadsheet of data collection to support the SCTOD). Table 1 below shows the change in red.**

| **Item ID** | **Information Collection Domain Sub-Type** | **Information Collection Update:** | **Proposed Information Collection Data Element Response Option(s)** | **Rationale for Information Collection Update** |
| --- | --- | --- | --- | --- |
| PRE245 | Disease Classification | Change/Clarification of Information Requested and Response Option | **MDS with defining genetic abnormalities** Myelodysplastic syndrome with low blasts and isolated 5q deletion (MDS-5q)  Myelodysplastic syndrome with low blasts and SF3B1 mutation (MDS-SF3B1)  Myelodysplastic syndrome with low blasts and ring sideroblasts (>=15% ring sideroblasts and wild type SF3B1)  Myelodysplastic syndrome with biallelic TP53 inactivation (MDS-biTP53)  **MDS, morphically defined** MDS, with low blasts (MDS-LB; <5% BM, <2%PB)  MDS, hypoplastic (MDS-h) <=25% cellularity by age  MDS with increased blasts (MDS-IB1)  MDS with increased blasts (MDS-IB2)  MDS with fibrosis (MDS-f)  **Childhood myelodysplastic neoplasms (MDS)** Childhood MDS with low blasts, hypocellular  Childhood MDS with low blasts, not otherwise specified  Childhood MDS with increased blasts  **Myelodysplastic/myeloproliferative neoplasms** hronic myelomonocytic leukemia (CMML), Myelodysplastic  Chronic myelomonocytic leukemia (CMML), Myeloproliferative  Myelodysplastic/myeloproliferative neoplasm with neutrophilia  Myelodysplastic/myeloproliferative neoplasm with SF3B1 mutation and thrombocytosis  MDS/MPN with ring siderobloasts (>=15% ring sideroblasts and wild type SF3B1) and thrombocytosis  Myelodysplastic syndrome / myeloproliferative neoplasm, NOS  **Transformed to AML** Transformed to AML | Capture data accurately |

**Attachments:**

1. Current SCTOD Information Collection – Spring 2024