HRSA
Health Resources & Services Administration
5600 Fishers Lane
Rockville, MD 20857

DATE: July 26, 2024

TO: Daniel Cline, OMB Desk Officer

FROM: Joella Roland, HRSA Information Collection Clearance Officer

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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	Capture data accurately

Item ID	Information Collection Domain Sub-Type	Information Collection Update:	Proposed Information Collection Data Element Response Option(s)	Rationale for Information Collection Update
			(CMML), Myeloproliferative Myelodysplastic/myeloproliferative neoplasm with neutrophilia Myelodysplastic/myeloproliferative neoplasm with SF3B1 mutation and thrombocytosis MDS/MPN with ring sidero bloasts (>=15% ring sideroblasts and wild type SF3B1) and thrombocytosis Myelodysplastic syndrome / myeloproliferative neoplasm, NOS **Transformed to AML** Transformed to AML	

Attachments:

1. Current SCTOD Information Collection – Spring 2024