

**DATE:** July 20, 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 make minor revisions to the post-transplant data collection to maintain current, effective, and efficient data collection. This memo explains the changes and supporting rationale.

**Changes:** The Center for International Blood and Marrow Transplant Research currently maintains information and complex reporting rules for subsequent infusions across three separate follow-up forms, affecting consistent and efficient data capture. Since subsequent infusions trigger a new event, the same information is collected at the pre-infusion time point. To increase efficiency and reduce redundant information collection, several questions are being removed from the post-hematopoietic cell transplantation (HCT) timepoint.

The question of one post-transplant variable is being modified to capture if a subsequent infusion was received, rather than a subsequent HCT. This will allow the collection of information necessary to set up a new event regardless of the infusion type. Several questions of other post-transplant variables will be removed from the post-HCT time point. The information found in these questions will continue to be collected at the pre-infusion time point for the subsequent infusion.

The overall scope of the updates to the post-transplant variables represents an update in the data collection process and will not impact any reports that support the program. See the “Change Summary” tab of Attachment 1 for more details.

**Time Sensitivity:** The SCTOD data collection changes must be completed in a timely manner to fulfill C.W. Bill Young Cell Transplantation Program requirements. These changes are considered non-substantive. Approval is

requested by May 17, 2024, to implement the changes in the data collection system in the scheduled Summer 2024 Quarterly Release. If this timeline is not met, the next release is scheduled approximately three months later.

**Burden:** The changes requested are non-substantive and do not substantially change the estimated reporting burden. They may even lead to nominal burden reduction by simplifying reporting for users.

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

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 (if applicable)	Proposed Information Collection Data Element Response Option(s)	Rationale for Information Collection Update
POST010	Post-Transplant Essential Data	Change/ Clarification of Information Requested	Did the recipient receive a subsequent HCT infusion?	no, yes	Capture data accurately
POST011	Post-Transplant Essential Data	Deletion of Information Requested	<del>Date of subsequent HCT:</del>	<del>YYYY/MM/DD</del>	Reduce redundancy in data capture
POST012	Post-Transplant Essential Data	Deletion of Information Requested	<del>What was the indication for subsequent HCT?</del>	<del>Graft failure / insufficient hematopoietic recovery, Insufficient chimerism, New malignancy (including PTLD and EBV-lymphoma), Other, Persistent primary disease, Planned subsequent HCT, per protocol, Recurrent primary disease</del>	Reduce redundancy in data capture
POST013	Post-Transplant Essential Data	Deletion of Information Requested	<del>Specify other indication:</del>	<del>open text</del>	Reduce redundancy in data capture
POST014	Post-Transplant Essential Data	Deletion of Information Requested	<del>Source of HSCs (check all that apply)</del>	<del>Allogeneic, related, Allogeneic, unrelated, Autologous</del>	Reduce redundancy in data capture
POST015	Post-Transplant Essential Data	Deletion of Information Requested	<del>Has the recipient received a cellular therapy? (e.g. CAR-T, DCI)</del>	<del>no, yes</del>	Reduce redundancy in data capture
POST016	Post-Transplant Essential Data	Deletion of Information Requested	<del>Was this infusion a donor lymphocyte</del>	<del>no, yes</del>	Reduce redundancy in data capture

			infusion (DLI)?		
POST017	Post-Transplant Essential Data	Deletion of Information Requested	Number of DLIs in this reporting period	==	Reduce redundancy in data capture
POST018	Post-Transplant Essential Data	Deletion of Information Requested	Are any of the products, associated with this course of cellular therapy, genetically modified?	no, yes	Reduce redundancy in data capture
POST019	Post-Transplant Essential Data	Deletion of Information Requested	Date of cellular therapy:	YYYY/MM/DD	Reduce redundancy in data capture

**Attachments:**

1. Current SCTOD Information Collections-May 2024