**DATE:** February 8, 2023

**TO:** Kelsi Feltz, OMB Desk Officer

**FROM:** Samantha Miller, 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 minor revisions to the pre-transplant and post-transplant data collection to maintain current and effective data collection. This memo explains the changes and supporting rationale.

Two **pre-transplant variables** are revised to include updates in the instructions. First, ‘none’ is added as a response option for the question “Additional drugs given (peri-transplant) period” (see Table 1, Item ID PRE001). Second, redundancy in the overall instructions with the specific question about clinical trials is removed (see Table 1, Item ID PRE564).

**Post-transplant variables** are similarly revised to remove redundant instructional text, including 17 instances of language referring to a date of last report in individual questions and to replace with instructional text at the top of the information collection, and to remove navigational instructions to enable the accurate collection of data regarding the use of additional cellular therapy. Finally, additional clarifying instructional text is added to improve data collection on chimerism results (see Table 2, Item ID POST076).

**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 nominal changes are considered non-substantive. Approval of these changes is needed by March 1, 2023, to implement the changes in the data collection system during the scheduled Spring 2023 release. If this timeline is not met, the next release of data collection forms is scheduled approximately three months later.

**Burden:** The changes requested are non-substantive and do not substantially change the estimated reporting burden for patients with these indications and may even lead to reductions in the burden by clarifying instructions for users.

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

**Further details can be found in Attachment 1 (complete spreadsheet of data collection to support the SCTOD).**

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| **Table 1: Proposed Changes to Pre-Transplant Variables**  |
| **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** |
| PRE001 | Additional Drugs Given In the Peri-Transplant Period | Change/Clarification of Response Options | ALG, ALS, ATG, ATS, Alemtuzumab, Defibrotide, KGF, Ursodiol, none | (check all that apply) | Capture data accurately |
| PRE564 | Pre-Transplant Essential Data | Change/Clarification of Information Requested | Is the recipient participating in a clinical trial?  | no, yes | Capture data accurately |

| **Table 2: Proposed Changes to Post-Transplant Variables**  |
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| **Item ID** | **Information Collection Domain Sub-Type** | **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? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST015 | Post-Transplant Essential Data |   | Change/Clarification of Information Requested and Response Option | Has the recipient received a cellular therapy? (e.g., CAR-T, DCI)  | no, yes  | Instruction text change to remove navigation instructions |
| POST025 | Post-Transplant Essential Data |   | Change/Clarification of Information Requested | Did acute GVHD develop? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST027 | Post-Transplant Essential Data | Graft vs. Host Disease | Change/Clarification of Information Requested | Did acute GVHD persist? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST043 | Post-Transplant Essential Data | Graft vs. Host Disease | Change/Clarification of Information Requested | Did chronic GVHD develop? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST045 | Post-Transplant Essential Data | Graft vs. Host Disease | Change/Clarification of Information Requested | Did chronic GVHD persist? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST054 | Post-Transplant Essential Data |   | Change/Clarification of Information Requested | Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST056 | Post-Transplant Essential Data |   | Change/Clarification of Information Requested | Did the recipient develop COVID-19 (SARS-CoV-2)? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST065 | Post-Transplant Essential Data | Allogenic Recipients of Cord Blood units, Beta Thalassemia, and/or Sickle Cell Disease | Change/Clarification of Information Requested | Were chimerism studies performed? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST076 | Post-Transplant Essential Data | Chimerism Study Performed | Change/Clarification of Information Requested | Method | PCR "Single nucleotide polymorphisms (SNPS) (includes quantitative PCR, real time PCR, sequencing, other), Fluorescent in situ hybridization (FISH) for XX/XY, Karyotyping for XX/XY, Other, Restriction fragment-length polymorphisms (RFLP), VNTR or STR, micro or mini satellite | Capture data accurately |
| POST084 | Disease Assessment at the Time of Best Response to HCT |   | Change/Clarification of Information Requested | Compared to the disease status prior to the preparative regimen, what was the best response to HCT? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST107 | Post-HCT Therapy |   | Change/Clarification of Information Requested | Was therapy given for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy.) |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST112 | Post-HCT Therapy |   | Change/Clarification of Information Requested | Did a fecal microbiota transplant (FMT) occur? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |
| POST119 | Relapse or Progression Post-HCT |   | Change/Clarification of Information Requested | Was intervention given for relapsed, persistent, or progressive disease? |  | Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for questions at this time point of data collection |

**Attachment:**

1. Current SCTOD Information Collections\_incremental changes 2023-01-06