DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

DATE: September 22, 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).

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						
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

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						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)		Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall

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				develop?		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),	Capture data accurately

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					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	
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		Instruction text (since date of last report) for the individual question is extraneous as it is applied in the overall instructions for

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				disease? (Include any maintenance and consolidation therapy.)		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