DATE: April 18, 2017

TO: Patrick Wells, OMB Desk Officer

Stephanie Mok, OMB Desk Officer

FROM: Lisa Wright-Solomon, 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 Collection (OMB #0915-0310, expires 1/31/2020).

Purpose: The Pre-Transplant Essential Data (pre-TED) Disease Classification Form 2402 is being modified to incorporate new cytogenetic and molecular data, split timepoints for better understanding of the patient's disease between diagnosis and transplant, and update response options to require checkbox completion only for responses that apply instead of yes/no for every option.

Time Sensitivity: The SCTOD data collection changes must be completed in a timely manner to fulfill Program requirements. To collect data on these forms by mid-July, approval of these changes is needed by June 15. The next release for data collection forms is scheduled approximately three months later.

Burden: The revisions included herein do not change the estimated reporting burden.

PROPOSED CLARIFICATIONS AND REVISIONS FOR STEM CELL THERAPEUTIC OUTCOMES DATABASE FORMS:

Form 2402

a. **Question 7 - Revision**
Replaced the option "Neurofibromatosis type 1" with "Dyskeratosis congenita."
Rationale: Determined that neurofibromatosis is not relevant to AML and dyskeratosis congenita is.

b. **Questions 9-78 – Reformatted**
Previously, cytogenetic abnormalities and molecular markers were included as individual questions (Q9-56 2402 R1) capturing all abnormalities at any time prior to the start of the preparative regimen. They are now reformatted and separated into distinct time points (at diagnosis, between diagnosis and last evaluation, and at last evaluation). Cytogenetic abnormalities are also split to identify those found via two relevant testing methods: karyotyping vs FISH.
Rationale: To provide more complete understanding of the patient's disease between diagnosis and transplant. The new 'check all that apply' format also allows for easier completion for data management staff.

c. **Questions 56 and 58 - Removed**
Removed molecular and cytogenetic detail questions around disease status.
Rationale: This information is now captured as raw data in new Q9-78, eliminating the need for data managers to interpret the medical record

d. **Question 79 – Addition**
Added Q79 "Did the recipient have central nervous system leukemia at any time prior to the start of the preparative regimen / infusion?"
Rationale: To provide better understanding of the disease for all patients and for appropriate risk adjustment.

e. **Question 81– Revision**
Changed from "How many cycles of induction therapy were required to achieve CR?" to "How many cycles of induction therapy were required to achieve 1st complete remission? (includes CRi, CRp)."
Rationale: To clarify the intent of the question for data management staff.

f. **Questions 86-88 - Addition**
Added questions capturing pre-disposing conditions.
Rationale: To harmonize with the AML section of the 2402.

g. **Questions 90-139 - Revision**
Previously, cytogenetic abnormalities and molecular markers were included as individual questions (Q66-99 2402 R1) capturing all abnormalities at any time prior to the start of the preparative regimen. They are now reformatted and separated into distinct time points (at diagnosis, between diagnosis and last evaluation, and at last evaluation). Cytogenetic abnormalities are also split to identify those found via two relevant testing methods: karyotyping vs FISH.

Rationale: To provide more complete understanding of the patient's disease between diagnosis and transplant. The new 'check all that apply' format also allows for easier completion for data management staff.

h. **Questions 102 and 104 - Removed**
Removed molecular and cytogenetic detail questions around disease status.
Rationale: This information is now captured as raw data in Q90-139 eliminating the need for data managers to interpret the medical record.

i. **Questions 140 - Addition**
Added Q140 "Did the recipient have central nervous system leukemia at any time prior to the start of the preparative regimen / infusion?"
Rationale: To provide better understanding of the disease for all patients and for appropriate risk adjustment.

j. **Question 141– Revision**
Changed from "How many cycles of induction therapy were required to achieve CR?" to "How many cycles of induction therapy were required to achieve 1st complete remission? (includes CRi, CRp)."
Rationale: To clarify the intent of the question for data management staff.

Attachments:

All revisions are indicated with tracked changes in the attached document

1. Pre-TED Disease Classification Form 2402 R2