

DATE: December 8, 2016
TO: Patrick Wells, OMB Desk Officer
FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

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 12/31/2019).

Purpose: The Pre-Transplant Essential Data (pre-TED) Form 2400 will be split into two separate forms, the Pre-TED 2400, and Pre-TED Disease Classification Form 2402. This format change provides increased flexibility in data collection and form updates.

Time Sensitivity: The SCTOD data collection must be completed in a timely manner in order to fulfil Program requirements. In order to collect data on these forms by mid-January, approval of these changes is needed by December 21. 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 2400

a. **Question 52 - Addition**

Added question “Specify the number of these products intended to achieve hematopoietic engraftment”.

Rationale: This will allow capture of more detailed data when a recipient receives an infusion of more than one product

Form 2402

a. **Question 2 - Revision**

Changed the option “Other acute leukemia” to “Acute leukemia of ambiguous lineage”

Rationale: To align with the new WHO disease classifications

b. **Questions 3, 64, and 107 – Revision**

Updated the disease options

Rationale: To align with the new WHO disease classifications

c. **Question 111 – Removed**

Removed question capturing Chronic Myelogenous Leukemia (CML) classification (formerly Q111)

Rationale: Determined to be unnecessary

- d. **Question 119 – Revision**
Changed the text from “What was the disease status at last evaluation prior to the start of the preparative regimen?” to “What was the disease status?”
Rationale: To harmonize with the CML disease insert
- e. **Question 120 – Addition**
Added question regarding level of response for CML disease status
Rationale: Collects information regarding molecular and cytogenetic detail questions around disease status; formerly asked as two questions
- f. **Questions 121 and 122 - Removed**
Removed molecular and cytogenetic detail questions around disease status (formerly Q121 and 122).
Rationale: This information is now captured as one question – question 120
- g. **Question 171 - Addition**
Added question to capture the original date of the MDS diagnosis if it has transformed to AML
Rationale: This was asked in previous versions of the form and found to be necessary

Attachments:

All revisions are indicated with tracked changes in the attached documents

1. Pre-TED 2400
2. Pre-TED Disease Classification Form 2402