DATE:	December 11, 2017
TO:	Julie Wise, 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 combine the Hodgkin Lymphoma (HL) and Non-Hodgkin Lymphoma (NHL) sections into one section and incorporate updated 2016 WHO disease classifications for these indications. This will provide consistency across forms and decrease form complexity by maintaining only one set of questions. We also believe this will simplify reporting for clinical research professionals and remove ambiguity for clinical research professionals who complete the forms. This will also save time from having to write in a new disease classification when a specific disease is not available on the form.

We have also added questions about the disease status before transplantation based upon PET scan results, and the number of lines of therapy. The first question is necessary to collect information about response consistent with current assessment standards. The second is essential to understanding disease status at transplant for risk adjustment. Both items are routinely available for patients with lymphoma.

Time Sensitivity: The SCTOD data collection changes must be completed in a timely manner to fulfill Program requirements. Because it is essential for CIBMTR to maintain consistency across its data collection forms, these changes also relate to changes on other CIBMTR forms used to support our cellular therapy initiatives. To collect data on this form by mid-January, approval of these changes is needed by *December 31, 2017*. The next release for data collection forms is scheduled approximately three months later.

Burden: The revisions included herein do not substantially change the estimated reporting burden about patients with these indications.

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

Form 2402

a. **Question 167, 213 MDS/MPN classification – Revision**
Updated the list based on the 2016 WHO classifications
Rationale: To capture the most up-to-date disease classification.

b. **Question 268 Lymphoma histology at HCT – Revision**
Combined the sub-disease lists for Hodgkin and Non-Hodgkin Lymphoma, and updated the list based on the 2016 WHO lymphoma classifications.
Rationale: To capture the most up-to-date disease classification.

c. **Question 270 Assignment of DLBCL – Addition**
Added new question to capture method of DLBCL assignment. This is only asked for two subtypes of diffuse large B cell lymphoma.
Rationale: To capture the most up-to-date disease classification.

d. **Questions 271 - Revision**
Text changed from "Is the non-Hodgkin lymphoma histology reported at diagnosis a transformation from CLL?" to "Is the lymphoma histology reported at transplant a transformation from CLL?"
Rationale: To update the question text in accordance with other changes in the form.

e. **Questions 272 - Addition**
Added question "Was any 17p abnormality detected?" to capture information related to 17p abnormality when CLL transforms to a lymphoma.
Rationale: To improve the data professionals' experience when completing the form.

f. **Question 273 – Revision**
Text changed from "Is the non-Hodgkin lymphoma histology reported a transformation from, or was it diagnosed at the same time as another lymphoma (not CLL)?" to "Is the lymphoma histology reported at transplant a transformation from a different lymphoma histology? (Not CLL)"
Rationale: To update the question text in accordance with other changes in the form.

g. **Questions 274- 276 – Addition**
Added questions to clarify the original lymphoma prior to transformation.

Rationale: To improve data quality

h. Questions 277-282–Addition
Added new questions to capture PET scan results and Deauville score for TED patients.
Rationale: To provide updated information routinely used for the prognostic scoring of lymphoma patients.

i. Question 284 Lines of therapy– Addition
Added Q284 "Total number of lines of therapy received (prior to HCT / infusion)" with the answer options "1 line", "2 lines", "3+ lines".
Rationale: To provide a clear picture of patient's disease and disease status, and to harmonize data collection standards with other international organizations collecting HCT data.

Attachments:

1. Disease Classification Form 2402 R2. Current, approved form.

2. Disease Classification Form 2402 R3. All changes highlighted in yellow are revisions and changes highlight in blue are additions in the attached document.