

DATE: March 30, 2021
TO: Josh Brammer, 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 10/31/2022).

Purpose: HRSA is requesting OMB’s approval to modify the Post-TED F2450 to remove content and transfer it to a different form:

- The primary and contributing causes of death are being removed from Form 2450 and the data will instead be captured on the Recipient Death Data Form 2900 (not currently OMB approved). The form has been included in this request to display the changes being made. This is a shift in previously OMB-approved content with minimal updates. It is essentially transitioning data previously captured on one form to capturing the same information on a separate, discrete form. By asking data professionals at transplant centers to complete Form 2900, in lieu of Form 2450, for all allogeneic recipients who have died, it effectively adds two questions to Form 2900. These two questions include Question 2 “Was cause of death confirmed by autopsy?” and Question 3 “Was documentation [autopsy report] submitted to the CIBMTR?” This is considered essential information that is very easy for data managers to locate in the medical record.
- This shift in content will mean adding Form 2900 to other collection forms for OMB approval. The form already exists at CIBMTR but was not employed to collect data on behalf of HRSA’s CWBYCTP. With this proposed change, Form 2900 will become required for completion for any HCT recipient who dies, and therefore will also require OMB approval. Capturing all death information on this single form allows CIBMTR to maintain one consistent set of questions applicable to all infusion types. This also decreases form complexity by utilizing a standard, consistent process in the way the data is collected. These changes simplify processes for data managers at reporting centers.

Time Sensitivity: The SCTOD data collection changes must be completed in a timely manner to fulfill program requirements. CIBMTR needs to have consistent data capture processes that apply to multiple infusion types. A similar split of form content was considered through an expedited review by OMB in November 2016 resulting in CIBMTR splitting the F2400 to create the 2400 and 2402 forms.

Burden: The changes included herein do not change the overall estimated reporting burden. The F2900 will be registered with a time to complete of 3 minutes with corresponding reductions in time from the F2450 at various time points. Based on mortality rates, the F2900 will only apply to about 30 percent of allogeneic recipients in the first year after HCT. The updated burden table is attached.

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

Form 2450

a. Question 2 – Update

Added floating text to the “dead” option to “Complete a F2900 – Recipient Death Data”.

Rationale: The F2900 will now be completed.

b. Cause of Death – Removal (moved)

Removed the primary and contributing cause of death questions (Qs 3-6 on the 2450 R5).

Rationale: A Recipient Death Data F2900 will now come due in FormsNet3 for completion, as the same information is captured on that form.

Form 2900

a. Question 2 & Question 3 – Update

“Was cause of death confirmed by autopsy” and “Was documentation submitted to CIBMTR” will be required for completion. This effectively adds two questions to what was previously captured on the F2450.

Rationale: Important information to capture that is easily located within the medical record.

b. Question 4 – Update

- Sub-section headers and options within alphabetized. The five most common causes of death remain at the top of the list.
- Updated all “HCT or cellular therapy” text to “infusion” text.
- Added new sub-section for “Toxicity” with two new options (“neurotoxicity [ICANS]” & “tumor lysis syndrome”).
- Updated “thromboembolic” option to “thromboembolism”.

Rationale:

- Alphabetization is standard CIBMTR form format.
- Utilize consistent language.
- These can be causes of death for cellular therapy recipients.
- Utilize correct language.

c. Question 6 – Update

- Sub-section headers and options within alphabetized. The five most common causes of death remain at the top of the list.
- Updated all “HCT or cellular therapy” text to “infusion” text.
- Added new sub-section for “Toxicity” with two new options (neurotoxicity [ICANS] & tumor lysis syndrome).
- Updated “thromboembolic” option to “thromboembolism”.

Rationale:

- Alphabetization is standard CIBMTR form format.
- Utilize consistent language.
- These can be causes of death for cellular therapy recipients.
- Utilize correct language.

Attachments:

1. Post-Transplant Essential Data F2450 R5. Current, approved form.
2. Post-Transplant Essential Data F2450 R6. All items removed are displayed with green strikethrough. All items highlighted in gray are proposed changes, and items highlighted in green are additions to the attached document.
3. Recipient Death Data F2900 R4. Form in current use.
4. Recipient Death Data F2900 R5. All items highlighted in gray are proposed changes, and items highlighted in green are additions to the attached document.
5. Updated burden table.