DATE: September 15, 2021

TO: Josh Brammer, 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 10/31/2022).

Purpose: To collect COVID-19 vaccine data, HRSA is requesting OMB's approval to modify both the Pre-Transplant Essential Data (Pre-TED) Form 2400 and Post-Transplant Essential Data (Post-TED) Form 2450 forms. Collecting these data pre-transplant will help to understand the landscape of patients who come to transplant vaccinated and how often vaccinated patients get infected. Post-transplant, this information can be used to assess the incidence of COVID-19 infection in relation to vaccine availability and timing. Understanding infection rates when different doses were received may help in recommending dosing regimens for BMT recipients. COVID-19 vaccine data will be accessible to data professionals via the medical record in most cases; however, an "unknown" option has been included for scenarios where the data cannot be located. Any additional burden is minimal, and the questions are anticipated to be asked only for approximately the next year.

For the Post-TED Form 2450, approval is being requested to change basic information regarding fecal microbiota transplantation, an innovative treatment that may occur in some HCT recipients. No substantial shift in time to complete these data collections is anticipated as this therapy is very rarely used among HCT centers.

Lastly, there are additional minor formatting and terminology updates to Form 2450 and Form 2400 as detailed below.

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. To enable accurate and timely collection of COVID-related data, we are requesting expedited review of the changes to this data collection package.

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

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

Form 2400

a. **Question 57 – Update**
   Moved "GRID" to be first ID listed (Q60 on F2400 R8).
   Rationale: Preferred ID to capture so should be listed first.
b. **Question 59 – Update**
   Updated "Non-NMDP unrelated donor ID" (Q58 on F2400 R8) to "Registry donor ID."
   Rationale: Updated per the World Marrow Donor Association (WMDA) guidelines. No change in question intent or how we collect the data, only a name change.
c. **Question 89 – Update**
   Updated text from "given" to "used."
   Rationale: Clarification.
d. **Questions 90-96 – Addition**
   Added questions to capture COVID-19 vaccine data.
   Rationale: Considered essential information to assess the frequency of recipients vaccinated pre-transplant.

Form 2450

a. **Section Header – Update**
   "Subsequent Transplant" to "Subsequent Infusion."
   Rationale: Utilize consistent language.
b. **Floating Text (above Q15) – Update**
   "HCT or cellular therapy" to "infusion."
   Rationale: Utilize consistent language.
c. **Question 26 – Update**
   "Date maximum overall grade of acute GVHD" (Q30 on F2450 R5) to "first date of maximum overall grade of acute GVHD."
   Rationale: Clarify intent is to capture the first instance in which the maximum grade was met if it occurred multiple times.
d. **Question 34 – Update**
   Removed "date estimated" checkbox (Q38 on F2450 R5).
   Rationale: Consistency across form questions. The Instruction Manual also provides clarification on how to report when the exact date is not known.
e. **Question 36 – Update**
   Removed "unknown" option (Q40 on F2450 R5).
   Rationale: The Instruction Manual clarifies to contact the physician to request documentation.

f. **Question 37 – Update**
Moved “date of maximum grade of chronic GVHD” (Q42 on F2450 R5) under current Q36 “maximum grade of chronic GVHD.”
Rationale: Accurate form flow.

g. Question 42 – Update
Added options for “Heparin” and “Enoxaparin (Lovenox)” (Q46 on F2450 R5).
Rationale: These were previously highly reported under the “other specify” field.

h. **Questions 48-54 – Addition**
Added questions to capture COVID-19 vaccine data.
Rationale: Considered essential information to understand infection rates.

i. Floating text (above Q55) – Update
Updated “HCT” text to “infusion.”
Rationale: Utilize consistent language.

j. Question 55 – Update
Updated “HCT or cellular therapy” text to “infusion”
Rationale: Utilize consistent language.

k. Floating text (above Q63)– Update
Updated “HCT” text to “infusion”
Rationale: Utilize consistent language.

l. NMDP donor ID – Removal
Removed field for “NMDP donor ID (Q63 on F2450 R5. Please note, Q63 is NOT visible on the 2450 R5 as the question is not visible in FormsNet3 now that the “GRID” should be used).
Rationale: GRID should now be utilized per WMDA guidelines.

m. Question 66 – Update
Moved “GRID” to be first ID listed (Q67 on F2450 R5).
Rationale: Preferred ID to capture so should be listed first.

n. Question 68 – Update
Updated “Non-NMDP unrelated donor ID” (Q65 on F2450 R5) to “Registry donor ID.”
Rationale: Updated per the WMDA guidelines. No change in question intent or how we collect the data, only a name change.

o. Question 70 – Update
Removed floating text for “(donor / infant)” (Q68 on F2450 R5) and updated question text to “donor date of birth” or “donor age.”
Rationale: Conciseness.

p. Question 71 – Update
Removed floating text for “(donor / infant)” (Q69 on F2450 R5) and updated question text to “donor sex.”
Rationale: Conciseness.

q. Section Header – Update

Updated section header from “Disease Assessment at the Time of Best response to HCT” to “Disease Assessment at the Time of Best response to Infusion.”
Rationale: Utilize consistent language.

r. Question 82 – Update

Updated “HCT” text to “infusion.”
Rationale: Utilize consistent language.

s. Section Header – Update

Updated section header from “Post-HCT Therapy” to “Post-Infusion Therapy.”
Rationale: Utilize consistent language.

t. Floating text (above Q105)– Update

Added text to state “In questions 105-109….”
Rationale: Instructional clarity.

u. Question 107 – Update

Added options “Brentuximab vendotin” and “Daratumumab (Darzalex)” and removed “chemotherapy” option (Q105 on F2450 R5).
Rationale: “Brentuximab vendotin” and “Daratumumab (Darzalex)” were highly reported under “specify other systemic therapy” field. The option for “chemotherapy” was removed, as the specific drug will be reported under “specify other systemic therapy” field.

v. Questions 110-113 – Addition

Added questions to capture if a fecal microbiota transplant occurred.
Rationale: Capture novel post-HCT therapy.

w. Section Header – Update

Updated section header from “Relapse or Progression Post-HCT” to Relapse or Progression Post-Infusion.”
Rationale: Utilize consistent language.

x. Floating text (above Q114)– Update

Updated “HCT” text to “infusion” text.
Rationale: Utilize consistent language.

y. Question 114 – Update

Updated “HCT” text to “infusion” text.
Rationale: Utilize consistent language.

z. Question 122- Update

Added options to “Daratumumb (Darzalex)” and “Venetoclax” (Q116 on F2450 R5).
Rationale: These were highly reported under the “specify other systemic therapy” field.

aa. Date of most recent disease assessment – Removal

Prior parent question (Q121 on F2450 R5).

Rationale: The date of assessment should be “known” so a parent question is no longer needed.

bb. Q127 – Update

“Date of most recent disease assessment” (Q122 on F2450 R5) to “date of assessment of current disease status.”

Rationale: Clarify intent.

Attachments:

1. Post-Transplant Essential Data F2450 R5. Current, approved form.

2. Post-Transplant Essential Data F2450 R6. All items removed are displayed with a red strikethrough. All items highlighted in yellow are proposed changes, and items highlighted in blue are additions to the attached document.

3. Pre-Transplant Essential Data F2400 R8. Current, approved form.

4. Pre-Transplant Essential Data F2400 R9. All items highlighted in yellow are proposed changes, and items highlighted in blue are additions to the attached document.