DATE: July 24, 2020

TO: Elizabeth Ashley, OMB Desk Officer

Quinn Hirsch, 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: The purpose of this request is to collect supplemental data about the potential impacts of COVID-19 pandemic on the HCT procedure for individual patients. Patients' procedures may be delayed or altered from the original planned cellular therapy in response to the pandemic, which may affect access to or outcomes of the transplant. The CIBMTR is interested in information related to the overall effects of the COVID-19 pandemic on transplant outcomes since March 1, 2020. The data collected will be used to: describe trends in use related to the pandemic, support future research projects, and risk-adjustment for the Center Specific Survival Analysis model for the CWBYCTP.

The data collected will be supplemental to the Pre-Transplant Essential Data (Pre-TED) Form 2400 and will be collected after the transplant has occurred. Data fields include: Intended transplant date, donor, product type, use of cryopreservation, and changes in the preparative regimen or graft-versus-host disease prophylaxis. Each transplant registered on Form 2400 with the CIBMTR will be included in the data collection for the COVID-19 impact to coordinate with existing data collection.

Process: Centers will be sent a weekly instruction email (no patient information), letting them know a data collection file is ready in our CIBMTR Portal, a secure file hosting site. Centers will log into Portal using established multifactor authentication protocols for security, to download the available file for data reporting. The file will be a spreadsheet called "PandemicImpact_CCNxxxxx" and will be pre-populated with the following patient identification fields, based on information already provided by the center on the Form 2400: CIBMTR Center Number,

CIBMTR Research ID, Infusion Date, Donor Type. Centers will enter responses to the questions in the spreadsheet and submit the completed file securely via our IT Service Now platform, which also uses multifactor security authentication. Submitted spreadsheets will be reviewed for completeness, accuracy and consistency by CIBMTR staff before being uploaded into our Integrated Data Warehouse (IDW). The data collected will be integrated in the CIBMTR database along with other information about the patient provided by the center.

CIBMTR intends to refresh the "PandemicImpact_CCNxxx" spreadsheet weekly to include cellular therapy recipients newly registered using existing data collection forms and remove recipients where requested data has been provided. The spreadsheet will be cumulative, and centers will be reminded on a weekly basis. CIBMTR has developed processes to receive and process information weekly if centers choose to report in that way, but weekly reporting is not required. Centers will continue to complete existing data collection forms in the standard way with existing response/turn-around times. These COVID-19 data are supplemental to those standard forms and processes, hence are coordinated with them. Because of the minimal nature of the supplemental data, centers may choose to complete the information in the spreadsheet more quickly, but they will not be expected to be completed any more frequently than existing forms.

CIBMTR plans to collect these data related to COVID-19 for the duration of the COVID-19 pandemic. CIBMTR will re-assess the data collection on a quarterly basis to determine the need to continue to receive these data. Once the COVID-19 pandemic has ended, and centers have returned to normal operations that are not disruptive of standard cellular therapy treatment procedures, CIBMTR will stop collecting these additional data fields and revert to collection of the Form 2400 without supplemental COVID-19 data.

Time Sensitivity: CIBMTR requests a response within 2 weeks of submission. The collection of these data is time sensitive because of the ongoing pandemic, to establish a pattern of data collection as soon as possible, and to minimize the backlog of collecting data from centers beginning March 1, 2020

Burden: CIBMTR has assessed reporting burden and determined that the requested supplemental data to be collected will not substantially change the

estimated reporting burden for centers. Using information from 6 centers who tested this approach, we estimate as many as half of HCT eligible patients, depending upon region of the country and prevalence rates of COVID-19, will not have any modifications to their cellular therapy procedure. For these patients, the additional time spent by the center per patient is nominal. For those patients with HCT pandemic-based treatment modifications, we also assessed additional reporting time necessary for this supplemental data collection with 6 centers and 46 patients. The median time per patient to complete the information was 6 minutes. Finally, these changes are not permanent as CIBMTR plans to stop the collection of these data once the pandemic is over, as mentioned above.

PROPOSED additional questions to be requested for recipients of cellular therapy for the SCTOD:
FORM 2400 COVID Supplemental Data

a. **Question 1 – Was the HCT impacted for a reason related to the COVID-19 (SARS-CoV-2) pandemic?**
   Rationale: Capture baseline information on HCT impacts as related to the COVID-19 pandemic in instances of both allogeneic and autologous transplantation.
   Response Options: Yes/No

b. **Question 2 – Original date of HCT (only completed when Q1 = Yes)**
   Rationale: Capture baseline information on HCT impacts as related to the COVID-19 pandemic.
   i. Provides an option for "date estimated" field for the original HCT date in case a specific date is not known.
   ii. Provides a "no change planned" option for the original HCT date.
   Response Options:
   i. Original date of HCT: Date
   ii. Date estimated: Yes or Blank
   iii. No change to planned HCT date due to COVID-19 pandemic: Yes or Blank

c. **Question 3 – Is the donor different than the originally intended donor? (only completed when Q1= Yes and Donor was ALLO)**
   Rationale: Capture instances of allogeneic transplantation where donor source had to change due to the COVID-19 pandemic.
   Response Options: Yes/No

d. **Question 4 – Specify the originally intended donor (only completed when Q3 = Yes and Donor was ALLO)**

Rationale: Capture original donor information in instances of allogeneic transplantation.
Response Options: Unrelated donor, Syngeneic, HLA-identical sibling, HLA-matched other relative, HLA-mismatched relative

e. **Question 5 – Is the product type (bone marrow, PBSC, single cord blood unit) different than the originally intended product type? (only completed when Q1 = YES and Donor was ALLO)**
Rationale: Capture product type changes due to COVID-19 pandemic in instances of allogeneic transplantation.
Response Options: Yes/No

f. **Question 6 – Specify the originally intended product type (only completed when Q5 = Yes)**
Rationale: Capture original product type information
Response Options: Bone marrow, PBSC, Single CBU, Other product

g. **Question 7 – Specify other product type (only completed when Q6 = other)**
Rationale: Capture new product type information
Response Options: Free Text

h. **Question 8 – Was the current product thawed from a cryopreserved state prior to infusion? (only completed when Q5 = Yes)**
Rationale: Capture demand needs for cryopreserved product in allogeneic transplantation due to the COVID-19 pandemic.
Response Options: Yes/No

i. **Question 9 – Did the preparative regimen change from the original plan? (only completed when Q1= yes and Donor was ALLO)**
Rationale: Capture instances of preparative regimen changes due to the COVID-19 pandemic in instances of allogeneic transplantation. In this case, CIBMTR is just interested in whether the preparative regimen was altered, but not the specific details of the intended preparative regimen.
Response Options: Yes/No

j. **Question 10 – Did the GVHD prophylaxis change from the original plan? (only completed when Q1 = yes and Donor was ALLO)**
Rationale: Capture instances of Graft-versus Host Disease (GVHD) prophylaxis changes due to the COVID-19 pandemic in instances of allogeneic transplantation. In this case, the CIBMTR is just interested in whether the GVHD prophylaxis was altered, but not specific details of the intended preparative regimen.
Response Options: Yes/No

Attachments:

1. Pandemic Impact Template