DATE: August 27, 2021

TO: Sharon Block, Acting Administrator
                 Office of Information and Regulatory Affairs
                 Office of Management and Budget

FROM: Diana Espinosa, Acting Administrator

SUBJECT: Request for Expedited Review – Stem Cell Therapeutic Outcomes
                 Database Collection (SCTOD)-OMB #0915-0310 Emergency Information
                 Collection

ISSUE

The Health Resources and Services Administration (HRSA) is requesting an expedited review to modify two forms currently approved under Office of Management and Budget (OMB) #0915-0310 (Pre-Transplant Essential Data (Pre-TED) Form 2400 and Post-Transplant Essential Data (Post-TED) Form 2450).

Data collected on these revised forms will help inform clinical and policymaking decisions for those who need blood stem cell transplants.

BACKGROUND

Because of the ongoing COVID-19 pandemic and its clinical implications, there is an urgent need to collect COVID-19 vaccine information on blood stem cell transplant patients. Collecting these data to include in the scientific database will help clinicians and researchers better understand the parameters around vaccinated blood stem cell transplant patients and their pre-and post-transplant responses to treatment.

In April 2020, HRSA made a similar request to add COVID-19 related questions to these forms, and OMB's prompt review and approval greatly assisted the blood stem cell transplantation community. Data were used by the Centers for Disease Control and Prevention (CDC) to make recommendations for prioritizing COVID-19 vaccinations. The data proposed in this request may also assist the CDC with its policymaking, including recommendations regarding COVID-19 vaccination boosters for those with suppressed immune systems and altered viral loads.

DISCUSSION

The Stem Cell Therapeutic and Research Act of 2005, Public Law 109–129, as amended, provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. It also maintains a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (e.g., bone marrow, cord blood, or other such product) from a donor.

To collect COVID-19 vaccine data, HRSA is requesting OMB's approval to modify both the Pre-TED Form 2400 and Post-TED Form 2450. The new data will enable an analysis of outcomes based on vaccine manufacturer/type, doses received (including potential boosters), and timing, and could influence future vaccination strategies.

Given the rapid evolution of COVID-19 and its impact on those with compromised immune systems, it is imperative for the transplant community to quickly collect and update COVID-19 related data. Having access to COVID-19 vaccination status on bone marrow recipients and understanding immune responses will help inform decisions regarding direct clinical care.

Notable Timing Factors:
HRSA would like to start requiring data collection no later than September 10, 2021. Given the rapid evolution of the COVID-19 public health emergency and its impact on immunocompromised patients, availability of new vaccines, and continual changes in vaccination recommendations, HRSA wants to leverage the required data collection platform of SCTOD to obtain vaccine information for all U.S. allogeneic hematopoietic stem cell transplant recipients.

Questions about vaccination status will likely become universal at transplant centers' intake for the next 12 months or more. For these reasons, HRSA believes the data will be readily available to data professionals working at transplant centers via medical records.

Although we expect these questions to be critical for the next 12 months, other COVID-19 related questions may be requested on these forms in the future.

Anticipated Reaction:
HRSA anticipates that the data collected will be useful for providers and other Federal agencies. It is anticipated that physicians will use this data to make clinical decisions and CDC would be able to make informed decisions regarding vaccine recommendations. Data collected prior to a patient's blood stem cell transplant will help to characterize frequencies of vaccination, and the level of protection afforded during and after transplant based on the incidence of COVID-19 infection. Post-transplant, this information can be used to assess vaccination rates and timing in blood stem cell recipients, characterize emerging vaccination strategies (which may include "boosters"), describe possible short and long-term side effects of vaccines, and analyze the incidence of COVID-19 infection based on different vaccination approaches.

Rollout:

HRSA will begin collecting the data as soon as approval is granted and plans to continue collecting this data over the next year; anticipating additional changes in the future as the science evolves.

Thank you for considering this expedited approval.

_____

Attachments

TAB A: PRA Emergency Clearance Package:
- *Supporting Statement A* document details this request and includes a reference to the attachment titled (*Att_1_03072019 The Stem Cell .pdf*) which is the last published 60-day FRN in 2019.
- Data collection forms to be revised which are the 2400 and 2450 forms. We have included the current versions in PDF and the revised versions in Word documents to show the track changes. The attachments are as follows:
  - *2400 R8 (current, approved for)*
  - *2400 R9*
  - *2450 R5 (current, approved for)*
  - *2450 R6*
- The following forms are part of the current data collection tool and are included because they are listed on the burden table.
  - *2004 R5 (current approved for)*
  - *2005 R7 (current approved for)*
  - *2006 R5 (current approved for)*
  - *2402 R6 (current approved for)*
- *Documentation with each project.* This attachment is completed for the whole information collection request.
- The following documentation for each form documents is included as requested. We have completed them for each form as requested and in the same manner, done in past OMB submissions
  - *6e-Documentation with each f*
  - *6d-Documentation with each f*
  - *6a-Documentation with each f*
  - *6f-Documentation with each f*