Supporting Statement A

Stem Cell Therapeutic Outcomes Database Collection (SCTOD)

OMB Control No. 0915-0310

Revision

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 blood stem cell recipients and understanding immune responses will assist with making informed decisions regarding direct clinical care. This will also inform critical policy decisions.

The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 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.

The SCTOD data collection changes must be captured and completed as soon as practical. 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 US allogeneic hematopoietic stem cell transplant (HCT) recipients.

2. Purpose and Use of Information Collection

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. Collecting these data will help clinicians and policymakers to understand the landscape of vaccination among immunocompromised patients before and after a blood stem cell transplant.

This information will be used to analyze outcomes based on vaccine manufacturer/type, doses received (including potential boosters), timing, and inform

future vaccination strategies. Information currently collected regarding COVID-19 infections has already been used in research studies.

Data collected prior to a patient receiving a blood stem cell transplant will be used to characterize frequencies of vaccination, and the level of protection afforded during and after transplant based on the incidence of COVID 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. This information may guide future vaccination strategies or COVID treatments. The vaccination status of recipients may also be useful for risk adjustment in the annual transplant center-specific analysis. For example, CDC advisors are looking for COVID-19 vaccination data on blood stem cell transplant recipients; however, collecting these data on existing OMB forms is not yet approved; therefore, this vital information has not been collected. The CDC could potentially use this information to make informed decisions regarding whether to issue any recommendations for this medically vulnerable population.

The additional COVID-19 vaccine questions will capture basic information on vaccination status, vaccine manufacturer/type, dose(s) given, and date(s) received. Patients who need a blood stem cell transplant are typically aware of their COVID-19 risk and vaccination status, and the information is also found on the vaccine cards carried by most recipients. Questions about vaccination status will likely become universal at transplant center 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 the medical record. To reduce burden, an "unknown" option has been included for scenarios where the data cannot be located, and a "date estimated" checkbox has been included when the exact date of vaccination is not known. Although these questions are anticipated to be asked over the next 12 months and then removed, other COVID-19 related questions may be requested for inclusion on these forms in the future given the rapid evolution of COVID-19 and its impact on immunocompromised patients, availability of new vaccines, and continual changes in vaccination recommendations.

3. Use of Improved Information Technology and Burden Reduction

There are no apparent technological solutions to facilitate collecting vaccination information that would reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

HHS is the primary federal entity authorized to oversee the national system of blood stem cell transplantation. Within HHS, HRSA DoT is responsible for administering the CW Bill Young Cell Transplantation Program. To the best of our knowledge, no other entity within the federal government has implemented or will implement a system used for data collection regarding COVID vaccination within the United States for HCT.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in the data collection related to COVID vaccination.

6. Consequences of Collecting the Information Less Frequently

HRSA is collecting the information at the most appropriate time points that have already been designed to minimize the frequency of data collection. These are the standard time points that we collect other data, and collecting less frequently would risk disrupting the existing system, or missing information. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the regulation as outlined above.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day Federal Register Notice was published in the Federal Register, 86 Fed. Reg. 67478, (November 26, 2021), see attachment 1. There were no public comments.

Section 8B:

HRSA program consulted with its SCTOD contractor in 2021 and obtained relevant information for this request. HRSA worked closely with the project director and project coordinator to complete this Emergency Information Request package to OMB. The SCTOD staff provided updated forms needed as well as an updated burden table. There are no other public contacts or opportunities for public comment apart from this solicitation. HRSA is not aware of any major problems during a consultation**.** Below are the names and contact information for those consulted:

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9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

The data collection instruments used for the SCTOD do not require information that could be used to directly identify transplant recipients. The SCTOD contractor utilizes a unique identification (ID) registration system for transplant recipients to avoid redundant reporting of transplant recipients across transplant centers and across time. This unique ID registration system exists within an isolated server and uses identifying information about transplant recipients provided by the transplant center to assign a unique ID number that does not contain personal identifiers. Subsequently, this unique number is used by the transplant center and other CWBYCTP components to exchange data regarding transplant recipients for purposes of reporting outcomes to the Government.

The ID registration system and the exchange of data between entities exist within the context of the designation of the SCTOD Contractor, CIBMTR, as a public health authority for purposes of the Health Insurance Portability and Accountability Act (HIPAA) as determined by the HHS Office of General Counsel and Office of Civil Rights (OCR) in fulfillment of the contract requirements (PHA letter attached). The Office of the General Counsel has determined, and OCR concurs, that the SCTOD Contractor meets the Privacy Rule's definition of a public health authority and is authorized by law to collect the information necessary for the SCTOD to fulfill its statutory purpose and functions. Under this analysis, transplant centers that are covered entities may disclose to the SCTOD contractor the individually identifiable health information collected by the SCTOD to comply with its statutory purposes. CIBMTR's research activities have oversight from its Institutional Review Board which is fully accredited by the Association for the Accreditation of Human Research Protection Programs.

The electronic systems used to create and maintain the unique ID system, and to collect and process data, exist under the auspices of HRSA's Office of Information Technology (OIT) Certification and Accreditation system. CIBMTR's data systems follow the Federal Information Systems Management Act of 2002 and the recommendations of the National Institute of Standards and Technology. The CIBMTR has a comprehensive and robust program to keep information and information systems safe. Detailed descriptions outlining how CIBMTR ensures the confidentiality and integrity of its information and information systems can be found at https://www.cibmtr.org/About/dataprotection/Pages/default.aspx.

Although the data collection instruments do not request direct identifiers, by virtue of the nature of reporting transplant outcomes required for the SCTOD contract, they request birth dates, procedure dates, complication and event dates, and death dates. CIBMTR does not release confidential data to external parties and de-identifies data before use whenever practical.

Data will be kept private to the extent allowed by law. This data collection is covered by a Certificate of Confidentiality from the National Institutes of Health. The

researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify a patient in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless the patient has consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if the patient has consented to the disclosure, including for medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by Health Resources and Services Administration (HRSA) or National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

All reports and tabulated data released to the general public are in the form of aggregate summaries of information across patients and transplant centers and do not contain identifying information.

11. Justification for Sensitive Questions

No questions of sensitive nature have been added to the current approval. Race ethnicity is already included.

12. Estimates of Annualized Hour and Cost Burden

Stem Cell Therapeutic Outcomes Database

Form Name	Number of Respondents[1]	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Baseline Pre-Transplant Essential Data (TED) (2400)	200	48	9,600	0.70	6,720
Disease Classification (2402)	200	48	9,600	0.43[2]	4,160
Product Form (includes Infusion (2006), HLA (2005), and Infectious Disease Marker inserts (2004))	200	45	9,000	1.00	9,000
100-day Post-TED (2450)	200	48	9,600	0.88	8,448
6 month Post-TED (2450)	200	43	8,600	0.85	7,310
1 year Post-TED (2450)	200	40	8,000	0.65	5,200
2 year Post-TED (2450)	200	34	6,800	0.65	4,420
3+ years Post-TED (2450)	200	172	34,400	0.52[3]	17,773
Total	**200**		**95,600**		**63,031**

1 The total of 200 is the number of centers completing the form; the same group will complete all of the forms.
2 The decimal is rounded down, and the actual number is .433333333.

3 The decimal is rounded up, and the actual number is .516667.

We anticipate two minutes or less will be required to complete questions about COVID vaccination. One

minute was added to the average burden response time for COVID vaccination questions; this estimates that 50% of recipients will be vaccinated pre-HCT and will require responses to all vaccination questions

Two minutes were added to the average burden response time for COVID vaccination questions; this was added at a one-time point only as the information will only be collected once

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal Government

The annual cost to the federal government for the SCTOD contract in FY 2020 was $4,601,550.

Additionally, HRSA obligated $4,730,240 to the SCTOD contract for FY2021. The information is collected as part of the SCTOD's contract requirements. The SCTOD is a firm fixed-price contract that HRSA awarded to the SCTOD contractor for five years in FY2017. The total cost of this contract is approximately $22,478,225.

15. Explanation for Program Changes or Adjustments

This request is to revise the data collection to include information about COVID vaccination in HCT recipients. The estimated additional burden of this revision is 448 hours.

Collecting these data will help clinicians and policymakers to understand the landscape of vaccination among immunocompromised patients before and after a blood stem cell transplant. This information will be used to analyze outcomes based on vaccine manufacturer/type, doses received (including potential boosters), timing, and inform future vaccination strategies. Information currently collected regarding COVID-19 infections has already been used in research studies.

16. Plans for Tabulation, Publication, and Project Time Schedule

This is no different than what already exists in this instrument.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and Expiration date will be displayed on every page of every form/instrument

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.