

DATE: July 27, 2024

TO: Daniel Cline, OMB Desk Officer

FROM: Joella Roland, 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 (SCTOD) Collection (OMB 0915-0310 expiration date 08/31/2025).

Purpose: The purpose of this request is to request minor revisions to the pre-transplant and post-transplant data collection to maintain current and effective data collection. This memo explains the changes and supporting rationale.

Changes: Ten pre-transplant and eight post-transplant variables were revised to disable questions concerning COVID-19 vaccinations, infection, and treatment. Feedback from data professionals indicated that it was increasingly difficult to locate and accurately report these data, especially regarding vaccinations. The system has received more than 3,600 tickets for support from more than 200 US transplant centers over more than 3 years since the COVID-19 vaccination-related questions were introduced. This number of queries from centers indicates a relatively moderate degree of difficulty in answering the questions.

Removing these questions will nominally decrease the burden for most respondents. See the “Change Summary” tab of Attachment 1, rows 2-19 for more details.

Seventeen pre-transplant variables were revised to include updates to the classifications of diseases by the World Health Organization (or similar international consensus organizations) and reflect the feedback from experts in the transplant community. While response options are changing, the overall number of questions is not. Additionally, individual respondents would only answer one or two of these questions with updated response options. Thus, the overall burden on individual respondents will not change. See the “Change Summary” tab of Attachment 1, rows 20-49 for more details.

A variable that is collected at both the pre-transplant and the transplant procedure/product time points is being modified to add the newly FDA-approved mobilizing agent “Motixafortide (Aphexda),” to the response option list. This will help establish a more complete list of selections and provide clarity for data users without changing the estimated reporting

burden. See the “Change Summary” tab of Attachment 1, rows 50-51 for more details.

Time Sensitivity: The SCTOD data collection changes must be completed in a timely manner to fulfill C.W. Bill Young Cell Transplantation Program requirements. These nominal changes are considered non-substantive. Approval of these changes is needed by February 14, 2024, to implement the changes in the data collection system during the scheduled Spring 2024 release. If this timeline is not met, the next release of data collection forms is scheduled approximately 3 months later.

Burden: The changes to remove COVID-19 related vaccine questions will reduce the information collection burden at the pre-transplant and first post-transplant time points by 1 minute and 2 minutes respectively per appropriate respondent. This is the same number of minutes added in August 2021 to the burden table when these questions were added to the information collection. The result of re-calculating the burden eliminated with the removal of these questions is within rounding error, resulting in no effective change in burden.

The changes requested to update disease classifications only affect response options for 16 questions without the addition of new questions. These changes may improve response accuracy and clarify the choices for respondents. However, they are not likely to measurably affect the response burden. Although response options include 16 questions, individual respondents will only complete one or two questions depending on the recipient’s disease. Therefore, the changes are non-substantive and do not substantially change the estimated reporting burden for patients with these indications.

Attachments:

1. SCTOD information collection spreadsheet, including change summary