

comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 18, 2016.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915-0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (P.L.) 109-129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, P.L. 114-104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to the U.S. Department of Health and Human Services (HHS). The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. The increase in burden is due to an increase in the annual number of

transplants and increasing survivorship after transplantation.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center-specific survival data.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Baseline Pre-Transplant Essential Data (TED)	200	44	8,800	1.15	10,120
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	33	6,600	1	6,600
100-Day Post-TED	200	44	8,800	1	8,800
6-Month Post-TED	200	36	7,200	1.15	8,280
12-Month Post-TED	200	32	6,400	1.15	7,360
Annual Post-TED	200	110	22,000	1.15	25,300
* Total	200	59,800	66,460

* The Total of 200 is the number of centers completing the form. The same group of 200 centers completes each of the forms.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.
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BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health

Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 17, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to

OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Network Allied Health Training Program Performance Improvement Measurement System (PIMS)

OMB No.: 0906-xxxx-NEW.

Abstract: The Rural Network Allied Health Training Program will support the development of formal, mature rural health networks that focus on activities that achieve efficiencies, expand access to, coordinate and improve the quality of essential health care services, and strengthen the rural health care system as a whole. This purpose will be achieved through the recruitment, clinical training, and retention of allied health professionals.

This program will further support integrated rural health networks that can partner with local community colleges and other accredited educational institutions (such as vocational and technical colleges) to develop formal clinical training programs.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. Several measures will be used for this program. All measures will speak to FORHP's progress toward meeting the goals.

Likely Respondents: The respondents are recipients of the Rural Network Allied Health Training Program grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Network Allied Health Training Program Performance Measures	10	1	10	6.55	65.5
Total	10	10	65.5

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License: The Development of an Anti-GPC3 Chimeric Antigen Receptor (CAR) Based on HN3 for the Treatment of Human Cancers

AGENCY: National Institutes of Health, Public Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in:

Intellectual Property: U.S. Provisional Patent Application 61/654,232 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012/0-US-01]; PCT Patent Application PCT/US2013/043633 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012/0-PCT-02]; Chinese Patent Application 201380039993.7 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012/0-CN-03]; Japanese Patent Application 2015-515243 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012/0-JP-04]; South Korea Patent Application 10-2014-7037046 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012/0-KR-05]; Singapore Patent Application 11201407972R entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref. E-136-2012/0-SG-06]; United States Patent Application 14/403,896 entitled “High-affinity Monoclonal Antibodies To Glypican-3 And Use Thereof” [HHS Ref.

E-136-2012/0-US-07]; and all continuing U.S. and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc.

The patent rights to these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be the United States, Australia, Canada, the European Union, Russia, China, Hong Kong, Japan, Taiwan, South Korea and Singapore, and the field of use may be limited to: “The development of a glypican-3 (GPC3) chimeric antigen receptor (CAR)-based immunotherapy using autologous (meaning one individual is both the donor and the recipient) primary human lymphocytes (T cells or NK cells) transfected with a lentiviral or retroviral vector, wherein the vector expresses a CAR having (1) a single antigen specificity and (2) comprising at least: (a) the complementary determining region (CDR) sequences of the anti-GPC3 antibody known as HN3; and (b) a T cell signaling domain; for the prophylaxis and treatment of GPC3-expressing cancers.”