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.

[FR Doc. 2016–11672 Filed 5–17–16; 8:45 am]

BILLING CODE 4165–15–P

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.''

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before June 2, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, National Cancer Institute, 9609 Medical Center Drive, Rm 1–E530 MSC9702, Rockville, MD 20850–9702, Email: *david.lambertson@nih.gov.*

SUPPLEMENTARY INFORMATION: This invention concerns an anti-GPC3 (Glypican-3) chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of GPC3-expressing cancers. GPC3 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly liver cancers such as hepatocellular carcinoma (HCC). The anti-GPC3 CARs of this technology contain (1) antigen recognition sequences that bind specifically to GPC3 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-GPC3 CAR can be transduced into T cells that are harvested from a donor, followed by (a) selection and expansion of the T cells expressing the anti-GPC3 CAR, and (b) reintroduction of the T cells into the patient. Once the anti-GPC3 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to GPC3-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 12, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–11659 Filed 5–17–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Survey To Assess the Feasibility of Establishing a Gynecologic Specimen Bank (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 8, 2016 page 12111 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Goli Samimi, Program Director, Breast and Gynecologic Cancer Research Group, Division of Cancer Prevention. 9609 Medical Center Drive, MSC 9783, Bethesda, MD 20892, or call non-toll-free number (240) 276–6582, or Email your request, including your address to: *goli.samimi@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Survey to assess the feasibility of establishing a gynecologic specimen bank (NCI), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute is assessing the feasibility of developing a tissue bank that would include tube and ovary tissues from women undergoing surgery for benign conditions, risk reduction and early stage cancer. Collecting tissues from tubes and ovaries containing clinically unsuspected precursors or early stage cancer is challenging, especially among women that are not at increased genetic risk. However, given that many pathology laboratories have enhanced their processing protocols for gynecologic surgical specimens removed for benign indications, it may be possible to develop a tissue resource. Accordingly, we are requesting information via a survey about the volume of samples that are accessioned at different pathology laboratories, and the methods used to process these samples. These data would provide information necessary to assess the feasibility of establishing a tissue bank for research and provide insights into the best design of a pilot study.

OMB approval is requested for 1 year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 42 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondent	Form name	Number of respondents	Frequency of response per respondent	Time per response (in hours)	Burden hours
Lab Managers	Survey	250	1	10/60	42