Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06498 Filed 3–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Theranostic Kits for mTOR Analog-based Chemotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to ProVivoX, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent, US Patent Application, and International Patent Application (and all foreign counterparts): US Provisional Patent Application Serial No. 61/144,501, filed 14 January 2009, entitled: ''Ratio-based Biomarker of Survival Utilizing PTEN and Phospho-AKT'' [HHS Reference No. E–025–2009/0–US–01]; International Application No. PCT/US2010/020944, filed on 13 January 2010, entitled: ''Ratio-based Biomarkers and Methods of Use Thereof'' [HHS Reference No. E–025–2009/0–PCT–02]; US Patent Application Serial No. 13/144,474, filed 13 July 2011 [HHS Reference No. E–025–2009/0–US–02]; and Canadian Patent Application No. 2,749,601, filed on 13 January 2010 [HHS Reference No. E–025–2009/0–CA–05]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be United States and Canada, and the field of use may be limited to:

a. ''Exclusive use of the Licensed Patent Rights to develop an immunohistochemistry (IHC)- or tissue microarray-based test kit for use with human tissue samples and approved in the United States and Canada as a Class III medical device, such test kit to be distributed in commerce for the for the purpose of predicting survival, response to therapy, or cancer recurrence in breast cancer patients.''

b. ''Non-exclusive use of the Licensed Patent Rights to develop an immunohistochemistry (IHC)- or tissue microarray-based test kit for use with human tissue samples and for which the United States FDA issues an order, in the form of a letter, which finds Licensee's kit to be a medical device substantially equivalent to one or more similar legally marketed devices, and states that the Licensee's device can be marketed in the U.S. (*i.e.,* 510(k) cleared), such test kit to be distributed in commerce for the purpose of predicting survival, response to therapy, or cancer recurrence in breast cancer patients.''

Upon the expiration or termination of the exclusive evaluation option license, ProVivoX, Inc., will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before April 7, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology describes a method of identifying cancer patients that may benefit from mTOR analog-based chemotherapy or agents directed against the AKT pathway.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization 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 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 evaluation 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: March 17, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–06487 Filed 3–20–15; 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 Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) 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 FR in Volume 79 on December 31, 2014 on page 78876 and allowed 60-days for public comment. One public comment was received that was a personal opinion regarding conducting research about the Brazil blood donation system. The purpose of this notice is to allow an additional 30 days for public comment. The 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: Desk Officer for NIH.

Comments 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: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge

Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301–435–0065, or Email your request, including your address to: *glynnsa@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV, in Blood Donors in Brazil 0925–0597, Expiration Date, July 31, 2015, Extension, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH)

Need and Use of Information Collection: Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among donors are critical steps to assessing and reducing risk of HIV transmission through blood transfusion. Detecting donors with recently acquired HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population. In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of incident HIV infections in blood donors serves important public health roles by identifying new HIV infections for anti-retroviral treatment, and enabling documentation of the rates of primary transmission of anti-viral drug resistant strains in the community. This study is a continuation of the current protocol that is approved by OMB, which expires on July 31, 2015, includes both a prospective surveillance and a case study designed to enroll eligible HIV seropositives detected at four participating blood centers in Brazil. This project is being conducted at the same four blood centers in Brazil, located in the cities of Sao Paulo, Recife, Rio de Janeiro and Belo Horizonte, but this time restricted to the study of HIV-positive subjects.

The primary study aims are to continue monitoring HIV molecular variants and risk behaviors in blood donors in Brazil, and to evaluate HIV subtype and drug resistance profiles among HIV-positive donors according to HIV infection status (recent versus long-standing infection), year of donation, and site of collection. Additional study objectives include determining trends in HIV molecular variants and risk factors associated with HIV infection by combining data collected in the previous REDS–II project with that which will be obtained in the planned research activities.

Given the initiation of NAT testing for HIV (and HCV) in Brazil, it will be important to continue to collect molecular surveillance and risk factor data on HIV infections. especially now that infections that might not have been identified by serology testing alone could be recognized through the use of NAT. NAT-only infections represent very recently acquired infections. The NAT assay will continue to be used at the four REDS–III blood centers in Brazil during the research activities. In addition, in order to distinguish between recent seroconversion and long-standing infection, samples from all HIV antibody dual reactive donations and/or NAT positive donations will continue to be tested by the Recent Infection Testing Algorithm (RITA) which is based on use of a sensitive/less-sensitive enzyme immunoassay (''detuned'' Enzyme Immunoassay). RITA testing will continue to be performed by the Blood Systems Research Institute, San Francisco, California, USA, which is the REDS–III Central Laboratory.

Since Dec 2012, the study has enrolled 223 HIV-positive donors (51 at Hemorio-Rio de Janeiro, 38 at Hemominas-Minas Gerais, 67 at Hemope-Pernambuco and 67 at Fundacao Pro-Sangue-Sao Paulo) with a target enrollment of 500 by 2017. It is important to continue the study and enroll more HIV infected donors to inform trend analyses. Preliminary evaluation of data has shown that respondent donors are completing the entire questionnaire including information about their risk behaviors. According to the Brazilian guidelines, blood donors are requested to return to the blood bank for HIV confirmatory testing and HIV counseling. Donors are invited to participate in the study through administration of informed consent when they return for HIV counseling. Once informed consent has been administered and enrollment has occurred, participants are asked to complete a confidential self-administered risk factor questionnaire by computer. In addition, a small blood sample is collected from each HIV-positive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing are communicated back to the HIV-positive participants during an in-person counseling session at the blood center. For those individuals who do not return for confirmatory testing, the samples will be anonymized and sent to the REDS–III Central Laboratory to perform the recent infection testing algorithm (RITA).

This research effort will allow for an evaluation of trends in the trafficking of non-B HIV subtypes and rates of transmission of drug resistant viral strains in low risk blood donors. These data could also be compared with data from similar studies in higher risk populations. Monitoring drug resistance strains is extremely important in a country that provides free anti-retroviral therapy for HIV infected individuals, many of whom have low level education and modest resources, thus making compliance with drug regimens and hence the risk of drug resistant HIV a serious problem. It is worth noting that Brazil is the first developing country to implement early treatment initiation for all individuals living with HIV/AIDS irrespective of CD4 count; this new universal treatment policy went into effect in 2014.

Findings from this study will be compared to trends in prevalence, incidence, and molecular variants from studies of the general population and high risk populations in Brazil, thus allowing for broader and more effective monitoring of the HIV epidemic in Brazil, as well as assessment of the impact of donor selection criteria on these parameters. We also propose to continue to examine trends in risk behaviors by comparing the data previously collected to the data we plan to collect for the next three year period. This will allow for extended trend analyses over a 10-year period that complements similar monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the USA and other funded international REDS–III sites in South Africa and China, thus allowing direct comparisons of these parameters on a global level.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 40.

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Risk Factor Informed Consent	Adult Donors	100	1	5/60	8

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Risk Factor Assessment	Adult Donors	100	1	19/60	40

Dated: March 11, 2015.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–06565 Filed 3–20–15; 8:45 am]

BILLING CODE 4141–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Expired Listing From Premerus PSO, LLC

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, (73 FR 70732–70814), provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. The listing from the Premerus PSO, LLC has expired and AHRQ has delisted the PSO accordingly.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on January 10, 2015.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.pso.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when the PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs. Premerus PSO, LLC, PSO number P0120, a component entity of Premerus, Inc., chose to let its listing expire by not seeking continued listing. Accordingly, Premerus PSO, LLC was delisted effective at 12:00 Midnight ET (2400) on January 10, 2015.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov/index.html.*

Dated: March 17, 2015.

Sharon B. Arnold,

Deputy Director, AHRQ.

[FR Doc. 2015–06454 Filed 3–20–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Commercial License Agreement: Development of 5T4 Antibody-Drug Conjugates for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an start-up exclusive commercial license to practice the inventions embodied in U.S. Patent Application No. 62/034,995 entitled ''Human Monoclonal Antibodies Specific for 5T4 and Methods of Their Use'' filed August 8, 20014 [HHS Ref. E–158–2014/0–US–01] and all related continuing and foreign patents/patent applications for the technology family to Concortis, Inc. The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective start-up exclusive commercial license territory may be worldwide and the field of use may be limited to the development of 5T4 antibody drug conjugate therapeutics for the treatment of human cancers using Concortis' proprietary conjugation technologies.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 7, 2015 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Whitney Hastings, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 451–7337; Facsimile: (301) 402–0220; Email: *hastingw@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: 5T4 is an antigen expressed in a number of