

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]
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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, 2014 [HHS Ref. E-158-2014/0-US-01] and all related continuing and foreign patents/patent applications for the technology family to Concertis, 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 Concertis’ 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

carcinomas. Its expression is limited in normal tissue, but is prevalent in malignant tumors throughout their development. This confined expression makes it an attractive target for cancer immunotherapy. 5T4 is often found in colorectal, ovarian, and gastric tumors and thus has been used as a prognostic aid for these cancers. In addition, its role in antibody-directed immunotherapy for delivering response modifiers to tumors has been studied using murine monoclonal antibodies (mAbs) and the cancer vaccine TroVax (currently in clinical trials for multiple solid tumors) targets 5T4. The present invention describes the identification and characterization of two fully human mAbs (m1001 and m1002) that bind to 5T4. Since the mAbs are fully human, they could have less immunogenicity and better safety profiles than the existing mouse and humanized antibodies.

The prospective start-up exclusive commercial license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective start-up exclusive commercial license may be granted unless within fifteen (15) days from the date of this published notice, 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.

Any additional, properly filed, and 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 commercial 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. 2015-06488 Filed 3-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Grantee Data Technical Assistance (GDTA) Training Needs Assessment Survey for SAMHSA Grantees-NEW

In 2014, the Center for Behavioral Health Statistics and Quality (CBHSQ) funded the GDTA contract to provide training and technical assistance to all grantees receiving funding from the Center for Substance Abuse Treatment (CSAT), the Center for Mental Health Services (CMHS), and some grantees receiving funding from the Center for Substance Abuse Prevention (CSAP)

that fall under the GDTA contract. This currently only includes discretionary grants but is expected to include block grants in future years. Training and technical assistance from the GDTA contract will focus on helping grantees use their Government and Performance Results Act of 1993 (GPRA) data for performance management and monitoring, and services improvement. The information being collected in this needs assessment will inform CBHSQ regarding the types of activities SAMHSA's grants use their funding for and what types of training activities they would like to receive in the future.

Description of Forms: Forms will include two questions. The first question asks about the services provided under the grant. Answer options include activities such as behavioral health care services, screening, prevention activities, and services to specific populations. The second question asks respondents to identify topics for training and technical assistance they would like to receive from a pre-populated list. Answer options include items such as data collection, data entry, and using data in creative ways. Both questions have an option for respondents to write-in an answer that is not included in the list.

Description of Respondents: The respondent universe for this data collection effort is one Project Director from each SAMHSA-funded grants being served by the GDTA contract. This currently only includes discretionary grants but is expected to include block grants in future years. There are currently 2,670 SAMHSA-funded discretionary grants served by the GDTA contract, therefore this is the number of respondents expected for this data collection effort.

TABLE 1—ANNUAL BURDEN ESTIMATE

Form name	Number of respondents	Annual responses per respondent	Total annual responses	Hours per response	Total annual hour burden
Grantee Needs Assessment	2,670	1	2,670	0.1	267

Written comments and recommendations concerning the proposed information collection should be sent by April 22, 2015 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit

their comments to OMB via email to: *OIRA_Submission@omb.eop.gov*. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory

Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,
Statistician.

[FR Doc. 2015-06532 Filed 3-20-15; 8:45 am]

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