

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.*

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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.*

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