

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

The prospective co-exclusive (or exclusive) start-up option licensed territory may be worldwide, and the field of use may be limited to:

The use of the monoclonal antibody SD1 (and glycoengineered variants thereof) as an antibody therapy for the treatment of mesothelioma, pancreatic cancer, breast cancer, ovarian cancer and lung adenocarcinoma. The Licensed Field of Use explicitly excludes the use of the antibody in the form of an immunoconjugate, including, but not limited to, immunotoxins.

Upon the expiration or termination of the co-exclusive start-up option license, MesoPharm Therapeutics, Inc. will have the co-exclusive right to execute a co-exclusive (or exclusive, if the other party declines their option) commercialization license which will supersede and replace the co-exclusive start-up option license with no greater field of use and territory than granted in the co-exclusive start-up option license.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 4, 2014 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated co-exclusive start-up option license should be directed to: David A. Lambertson, 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) 435-4632; Facsimile: (301) 402-0220; Email: [lambertson@mail.nih.gov](mailto:lambertson@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This invention concerns a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, ovarian cancer and pancreatic cancer. The specific antibody covered by this technology is designated SD1, which is a single domain, fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The SD1 antibody can selectively bind to these cancer cells and induce cell death 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 co-exclusive start-up option license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective co-exclusive start-up option 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 co-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: July 14, 2014.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: Multi-Site Evaluation of the Safe Schools/Healthy Students (SS/HS) State Program—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) will conduct the multi-site evaluation of the Safe Schools/Healthy Students (SS/HS) state program. The data collected through the multi-site evaluation addresses three study components: (1) The planning, collaboration, and partnership study; (2) the implementation study; and (3) the workforce study.

The SS/HS state program funded grantees in seven states beginning in September 2013. Data will be collected from state/tribal administrators, Local Education Authorities (LEAs)/Districts, local program staff (e.g., school resource officers, teachers and administrators, and psychologists) and program partners (e.g., parents, representatives from the juvenile justice and mental health providers).

Data collection activities will include key informant interviews, and web-based surveys. The instruments to be used for data collection are as follows:

#### *Planning, Collaboration and Partnership Study*

- State Key Informant Interview Protocol.
- District Key Informant Interview Protocol.
- State Collaborator Survey.
- District Collaborator Survey.
- State Collaboration Indicator Data Instrument.
- District Collaboration Indicator Data Instrument.

#### *Implementation Study*

- State & District Key Informant Interview Protocol.
- School-Level Survey.

#### *Workforce Study*

- No additional instruments will be used for this study. Data will be gathered from the Planning, Collaboration and Partnership Study and the Implementation Study.

A summary table of the number of respondents and respondent burden has also been included.

#### Data Collection Activities for MSE Grantees

Data for all instruments will be collected annually with the exception of data for the state and District

Collaboration Indicator Data Instrument which will be collected quarterly.

#### **State Key Informant Interview (Planning, Collaboration and Partnership Study)**

The key informant interview protocol will collect information on the service model, partnerships and interagency collaboration, program implementation fidelity, plan deviations, and state and local policy development at the state level. Interviews will also include questions to learn about opportunities that were provided for workforce training. Responses will be compared over time to assess positive development of the program model, emerging barriers and facilitators to implementation, and evolving solutions. On average, 14 state administrators will be interviewed annually and the duration of the interview is estimated to be one hour.

#### **District Key Informant Interview (Planning, Collaboration and Partnership Study)**

The purpose of these interviews is to identify, through the perspectives of LEA administrators and program partners their descriptions of SS/HS program activities. In particular, the degree to which critical SS/HS framework elements are operationalized, as well as the degree to which principles and strategies are acknowledged and integrated as part of the service processes. Topics include the provider's approach to service provision (sensitivity to health disparities, cultural competence), the coordination of services across the LEA and other local agencies, training of mental health workers, local policy and protocol development, and barriers/facilitators at the local level that influence the adoption, integration, and sustainability of SS/HS principles. Responses will be compared over time to assess positive development of the program model. It is anticipated that an average of 63 district administrators and program partners will participate in the interview each year and the interviews will be about one hour in duration.

#### **State Collaborator Survey (Planning, Collaboration and Partnership Study)**

The state administrator's survey will seek to understand the level of inter-professional collaboration among entities working at the state level to promote expanded school mental health. The survey will also capture perceptions of partnership functioning in terms of partner goals, resources, culture and values, and roles and responsibilities, as well as leadership

and collaboration among partners as they impact (1) school and community partner engagement, (2) facilitators, (3) barriers, (4) shared decision-making, (5) partnership structure, and (6) sustainability. An average of 208 state administrators and program partners will complete the survey annually and it is estimated that completion will take 30 minutes.

#### **District Collaborator Survey (Planning, Collaboration and Partnership Study)**

The state administrator's survey will seek to understand the level of inter-professional collaboration among entities working at the district level to promote expanded school mental health. The survey will also capture perceptions of partnership functioning in terms of partner goals, resources, culture and values, and roles and responsibilities, as well as leadership and collaboration among partners as they impact (1) school and community partner engagement, (2) facilitators, (3) barriers, (4) shared decision-making, (5) partnership structure, and (6) sustainability. An average of 624 LEA district administrators and program partners will complete the survey annually and the time for completion is estimated to be 45 minutes.

#### **State Collaboration Indicator Data Instrument (Planning, Collaboration and Partnership Study)**

The State Collaboration Indicator Data Instrument will gather data about the program activities that occur at the state level. By tracking these activities, it will be possible to determine the frequency with which administrators engage in SS/HS program related activities such as holding meetings, the number of persons who attend such meetings, whether and the frequency with which trainings and other support activities occur as well as the participants in such trainings. The instrument will also track whether and what type of resources are leveraged by program partners at the state level. One instrument will be completed by each state and it is estimated that it will take on average 1.5 hours to gather the data and complete the instrument.

#### **District Collaboration Indicator Data Instrument (Planning, Collaboration and Partnership Study)**

The District Collaboration Indicator Data Instrument will gather data about the program activities that occur at the LEA/district level. By tracking these activities, it will be possible to determine the frequency with which LEA administrators and program partners at the district level hold

meetings, the number of persons who attend such meetings, whether and the frequency with which trainings and other support activities occur, and the participants in such trainings. The instrument will also track whether and what type of resources are leveraged by program partners at the district level. One instrument will be completed by each of the 21 LEAs and it is estimated that it will take on average 1.5 hours to gather the data and complete the instrument.

#### **State and District Key Informant Interview (Implementation Study)**

The State and District Key Informant Interviews will be held with administrators and program partners at the state and LEA districts. The interviews will seek to gain an understanding of respondents' perspectives as these relate to the degree to which critical SS/HS framework elements are operationalized, as well as the degree to which mental health principles and strategies are acknowledged and integrated as part of the service processes. The interviews will also seek to gain an understanding of the types of services and supports that have been implemented as a result of the SS/HS program, children's access to mental health services, and the facilitators and barriers to program implementation. Interviews will also include questions to learn about the role workforce development opportunities played in program implementation. A total of 56 persons will be interviewed: 14 at the state/tribal level and 42 at the district level. Interviews will take on average one hour to complete.

*School-Level Survey (Implementation Study):* The school-level survey will be completed by persons who work within the schools that are participating in the SS/HS state program. The survey combines items from three surveys: **The Evidence-Based Practice Attitude Scale (EBPAS)** assesses mental health and social service provider attitudes toward adopting evidence-based practices. **The Mental Health Service Integration Survey (MHSIS)** assesses professional school mental health roles, service integration, and barriers and facilitators of mental health service integration in schools. **The School Mental Health Quality Assessment Questionnaire (SMHQAQ)** is a 40 item instrument divided into 10 domains that assess the integration of school mental health services delivered in schools. The 10 domains related to the 10 principles of expanded school mental health include: (1) Access to care; (2) Needs assessment; (3) Evidence-based practices; (4) Stakeholder involvement and feedback;

(5) Quality assessment and improvement; (6) Continuum of care and referral processes; (7) Clinician training, support, and service delivery; (8) Competently addressing developmental, cultural, and personal differences; (9) Interdisciplinary collaboration and communication; and (10) Community coordination. **The School Mental Health Capacity Instrument** is a 27-item scale that assesses the capacity of schools to address the mental health needs of students. The schools can be rated along

a continuum using the three individual subscales of intervention, early recognition & referral, or prevention & promotion. In addition, the total sum of all three scales provides an overall measure of capacity. The intervention subscale looks at training, protocols, and the designation of specific follow-up procedures for children referred for mental health services. Early recognition and referral covers universal screenings for potential problems, and communication between staff members to discuss students who may be

experiencing mental health concerns. Finally, prevention and promotion looks at the efforts focused on student's social-emotional development. A total of 2,100 persons will be invited to complete the survey annually and it is estimated that completion of the survey will take on average 25 minutes.

Internet-based technology will be used for collecting data via Web-based surveys, and for data entry and management. The average annual respondent burden is estimated below.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

Type of respondents	Instrument	Number of respondents	Responses per respondent	Average hours per respondent	Total annual hour burden
<b>Planning, Collaboration &amp; Participation Study</b>					
Key project staff at state level (e.g., project coordinators, evaluators), SMT members.	State Kills .....	14	1	1	14
Key project staff at LEA level (e.g., project coordinators, evaluators), CMT members.	District Kills .....	63	1	1	63
Key project staff at state level (e.g., project coordinators, evaluators), SMT members.	State Collaborator Survey ...	208	1	.5	104
Key project staff at LEA level (e.g., project coordinators, evaluators), CMT members.	District Collaborator Survey	624	1	.33	206
Project Evaluator .....	State Collaboration Indicator Data Instrument.	7	4	1.5	42
Project Evaluator .....	District Collaboration Indicator Data Instrument.	21	4	1.5	126
<b>Implementation Study</b>					
Program and school staff working at the state & district level.	Kills .....	56	1	1	56
Program and school staff working at the school level.	School-Level Survey .....	* 2,100	1	.45	945
Total .....	.....	3,093	.....	.....	1,556

\* 10 respondents will participate in up to 10 schools in each of the 21 LEAs.

The estimate reflects the average annual number of respondents, the average annual number of responses, the time it will take for each response, and the average annual burden. The number of grantees in each year is assumed to be constant.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2-1057, One Choke Cherry Road, Rockville, MD 20857 OR email her a copy at [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received by September 16, 2014.

**Summer King,**  
Statistician.

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5758-N-10]

**60-Day Notice of Proposed Information Collection: Authority To Accept Unsolicited Proposals for Research Partnerships**

**AGENCY:** Office of the Assistant Secretary for Policy Development and Research, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* September 16, 2014.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410-5000; telephone 202-402-5564 (this is not a toll-free number) or email at [Colette.Pollard@hud.gov](mailto:Colette.Pollard@hud.gov) for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street