

Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2314, Bethesda, MD 20892, (301) 496-8535, dhann@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 19, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-17423 Filed 7-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of invention: Novel metastatic serous epithelial ovarian cancer (SEOC) genetically engineered mouse models,

cell lines, and orthotopic models based on Rb, p53 and/or Brca 1/2 inactivation useful for biomarker discovery and preclinical testing.

Description of Technology: The high mortality rate from ovarian cancers can be attributed to late-stage diagnosis and lack of effective treatment. Despite enormous effort to develop better targeted therapies, platinum-based chemotherapy still remains the standard of care for ovarian cancer patients, and resistance occurs at a high rate. One of the rate limiting factors for translation of new drug discoveries into clinical treatments has been the lack of suitable preclinical cancer models with high predictive value.

NCI CAPR has developed Tri-allelic K18-T121^{tg/+}/Brca1^{fl/fl}/p53^{fl/fl} SEOC GEM Model, GEM-derived SEOC orthotopic mouse model, and biological materials derived therefrom, with several key histopathologic, immunophenotypic, and genetic features of human SEOC. SEOC GEMs were utilized to create orthotopic immunocompetent transplant models, and to generate synchronized cohorts of mice suitable for preclinical studies. NCI CAPR conducted studies that determine these models are tractable for use in routine efficacy studies and demonstrate the utility of these models in evaluating the potential efficacy of novel therapeutics for ovarian cancer.

Potential Commercial Applications:

- These models serve as a foundation for preclinical research and evaluation of efficacy of novel therapeutics for ovarian cancer.
- The GEM models described here can be used to develop cell lines and allograft models for evaluating drug potency relative to Brca1 mutation status.
- These mouse models provide the opportunity for evaluation of effective therapeutics, including prediction of differential responses in Brca1-wild type and Brca1-deficient tumors and development of relevant biomarkers.

Value Proposition:

- Novel resource for evaluating disease etiology and biomarkers, therapeutic evaluation, and improved imaging strategies in epithelial ovarian cancer
- Similarity to human ovarian cancer based on transcriptional profiling
- Suitable preclinical cancer models with high predictive value.

Development Stage: Pre-clinical (in vivo validation).

Inventor(s): Simone Difilippantonio, Terry Van Dyke, Zoe Weaver Ohler, Ludmila Szabova, Sujata Bupp, Yurong Song, Chaoying Yin.

Intellectual Property: Research use—no patent protection will be sought.

Publications:

1. Szabova L., Yin C., Bupp S., *et al.* Perturbation of Rb, p53 and Brca1 or Brca2 cooperate in inducing metastatic serous epithelial ovarian cancer. *Cancer research*. 2012;72(16):4141-4153.
2. Szabova L., Bupp S., Kamal M., *et al.* Pathway-Specific Engineered Mouse Allograft Models Functionally Recapitulate Human Serous Epithelial Ovarian Cancer. Kato M., ed. *PLoS ONE*. 2014;9(4):e95649.

Collaboration Opportunity:

Researchers at the NCI seek licensing and/or co-development research collaborations for the commercialization of agents for the treatment of SEOC.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: July 11, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-17419 Filed 7-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Pediatric Heart Network Clinical Research Centers (UG1).

Date: August 17-18, 2016

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Circle Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892 sunnarborgsw@nhlbi.nih.gov

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 19, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: August 30, 2016.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 9100, Bethesda, MD 20892 (Teleconference).

Contact Person: Valerie L. Prenger, Ph.D., MPH, Acting Division Director, Division of

Extramural Research Activities, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7214, Bethesda, MD 20892-7924, 301-435-0270, prengerv@nhlbi.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/nhlbac/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 19, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

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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: Mental Health First Aid Evaluation-NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) is requesting approval from the Office of Management and Budget (OMB) for new data collection

activities associated with its Mental Health First Aid (MHFA) program.

This information is needed to evaluate implementation of MHFA and Youth Mental Health First Aid in three distinct grant programs: Project Advancing Wellness and Resilience in Education (AWARE) State Education Agency (SEA) Cooperative Agreements, which provide funding to support MHFA and YMHFA training to state education agencies; Project AWARE Local Education Agency (LEA) Grants, which provide funding to school districts; and Project AWARE Community (C), a new funding opportunity in fiscal year 2015 that is intended to support MHFA and YMHFA training through a wide range of community organizations.

The MHFA/YMHFA evaluation will address both overarching and program-specific questions related to the implementation and effectiveness of widespread dissemination of mental health literacy programs through these three distinct funding mechanisms and increase SAMHSA's understanding of training, referral benefits, and issues in varied milieu (e.g., implementation climate, leadership). These evaluation questions are essential to address because, although MHFA/YMHFA has a track record and well-articulated theory of action, it is vital for SAMHSA to be able to identify factors that are expected to increase or decrease the extent MHFA/YMHFA is disseminated and implemented with quality.

This data collection is covered under the requirements of Public Law 103-62, the Government Performance and Results Act (GPRA) of 1993, Title 38, section 527, Evaluation and Data Collection, as well as 38 CFR 1.15, Standards for Program Evaluation.

SAMHSA is requesting clearance for four data collection instruments:

- (1) MHFA/YMHFA Pre-Training Survey
- (2) MHFA/YMHFA Post-Training Survey
- (3) MHFA/YMHFA 3-Month and 6-Month Follow-Up Survey
- (4) Qualitative protocol for interviews with site coordinators

The table below reflects the annualized hourly burden.

Instrument/Activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
MHFA/YMHFA Pre-Training Survey	22,800	1	22,800	.33	7,524
MHFA/YMHFA Post-Training Survey	22,800	1	22,800	.25	5,700
MHFA/YMHFA 3-Month Follow-Up Survey	19,380	1	19,380	.17	3,294
MHFA/YMHFA 6-Month Follow-Up Survey	17,100	1	17,100	.17	2,907
Qualitative Interviews	23	1	23	.75	17.25