metabolite does not inhibit the non-competitive glutamatergic N-methyl-D-aspartate (NMDA) receptor, and it exerts rapid actions that activate the α-amino 3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) receptors. Results indicate a non-NMDA receptor dependent mechanism underlying ketamine's antidepressant properties, which involve bioactivity of a specific metabolite (2R, 6R-HNK) could be exploited for drug development. Additionally, the researchers have established appropriate salt, crystal and polymorph forms of the agent and multiple methods of synthesis. Full ADME and polypharmacology assessment is complete as well as pre-formulations studies.

To expedite the research, development and commercialization of 2R,6R-hydroxynorketamine (a metabolite of ketamine), the National Institutes of Health, UMB and their collaborators are seeking one or more CRADA and/or license agreements with appropriate pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed technology and its public sector objectives, as outlined below. The purpose of a CRADA is to find a partner to collaborate in the development and commercialization of a technology that is in early phases of clinical development. Under the CRADA, key activities related to the clinical development of 2R,6R-HNK as a therapeutic to treat a variety of mental health conditions including depressive disorders will be performed. Collaborators should have proven experience in drug development with specialized expertise within depression and/or related mental health disorders. Owing to NIH's commitment to public dissemination of data, a key criterion will be that all outcomes from the collaborative effort will be published including the outcomes of all clinical trials. Further, it is the goal of NIH, UMB and other collaborators to develop the technology to the fullest extent (as therapeutic for multiple clinical indications including, but not limited to, anxiety, suicidal ideation, anhedonia, PTSD, addiction, neuropathic pain, among others).

How to Apply: Interested potential CRADA collaborators will receive detailed information on the current status of the project after signing a confidentiality disclosure agreement (CDA) with NIH, UMB and other collaborators. Interested candidate partners must submit a statement of interest and capability, no more than five pages long, to the NCATS point of contact before January 3, 2017 for consideration. Guidelines for the preparation of a full CRADA proposal will be communicated by the NIH to respondents that have demonstrated sufficient mutual interests and capabilities that indicate the partnering entity will appropriately and substantially contribute to the proposed collaboration. Capability statements submitted after the due date may be considered if a suitable CRADA collaborator has not been identified by NIH and UMB among the initial pool of respondents.

Respondents interested in submitting a CRADA proposal should be aware that it may be necessary for them to secure a patent license to the background-patent applications in order to commercialize products arising from a CRADA. Licensing of background technology patent rights related to this CRADA opportunity and claimed in the pending patent applications are available for either exclusive or non-exclusive licensing and licensing by NIH is subject to 35 U.S.C. 207 and 37 CFR part 404. CRADA partners are afforded an option to negotiate an exclusive license from the NIH for inventions arising from the performance of the CRADA research plan.

The full CRADA proposal should include a capability statement with a detailed description of: (1) Collaborator's Expertise with mental health disorders such as depression, (2) Collaborators' expertise in preclinical development efforts including toxicology and chemistry, manufacturing and controls (CMC), (3) Expertise in regulatory affairs, particularly at the IND filing and early stage clinical trials stages, (4) Collaborator's ability to support, directly or through contract mechanisms, and upon the successful completion of relevant milestones, the ongoing pharmacokinetics and biological studies, long term toxicity studies, process chemistry and other pre-clinical development studies needed to obtain regulatory approval of a given therapy so as to ensure a high probability of eventual successful commercialization and; (5) Collaborator's ability to provide adequate funding to support some pre-clinical studies of the project as well as clinical trials.

Publications

Zanos P, Moaddel R, Morris PJ, Georgiou P, Fischell J, Elmer GI, Manickavasagom A, Yuan P, Pribut HJ, Singh NS, Dossou KSS, Fang Y, Huang X–P, Mayo CL, Wainer IW, Albuquerque EX, Thompson SM, Thomas CJ, Zarate CA, Gould TD. NMDA receptor inhibition-independent antidepressant actions of a ketamine metabolite. Nature, May 4, 2016, doi: 10:1038/nature17998.

Patent Status

(1) ''Use Of (2R,6R)-HNK, (S)-Dehydronorketamine and (R,S)-ketamine metabolites in the treatment of depression and neuropathic pain''; Irving W. Wainer, Ruin Moaddel, Michel Bernier, Carlos A. Zarate, Mary Tanga, Marc C. Torjman, Michael Goldberg; Assignees: National Institute of Aging (NIA), National Institute of Mental Health (NIMH), SRI International, University of Medicine and Dentistry of New Jersey (UMDNJ); U.S. Provisional Patent Application # 61/547,336; Filed: October 14, 2011; NIH Reference # E–092–2011.

(2) ''Methods of using (2S,6S)-HNK and (2R,6R)-HNK to treat various depressive disorders and anxiety disorders''; Craig Thomas, Todd D. Gould, Irving W. Wainer, Carlos A. Zarate, Ruin Moaddel, Patrick Morris, Panos Zanos; Assignees: National Institute of Aging (NIA), National Institute of Mental Health (NIMH), National Center for Advancing Translational Sciences (NCATS), University of Maryland at Baltimore (UMB); U.S. Provisional Patent Application # 62/313317; Filed: March 25, 2016; NIH Reference #E–036–2016.

(3) ''Crystal forms and methods of synthesis of (2R, 6R)-HNK and (2S,6S)-HNK''; Craig Thomas, Patrick Morris, Carlos A. Zarate, Ruin Moaddel, Todd D. Gould, Panos Zanos; Assignees: National Center for Advancing Translational Sciences (NCATS), National Institute of Mental Health (NIMH), National Institute of Aging (NIA), University of Maryland at Baltimore (UMB); U.S. Provisional Patent Application #62/313309; Filed: March 25, 2016; NIH Reference #E–116–2016.

Dated: October 31, 2016.

Pamela McInnes,

Deputy Director, Office of the Director, National Center for Advancing Translational Sciences.

[FR Doc. 2016–26628 Filed 11–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; SBIR: Development of Cancer Therapeutics.

Date: December 5–6, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Reston, 11810 Sunrise Valley Drive, Reston, VA 20191.

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, *chatterm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.

Date: December 6, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, *bennettc3@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Mechanisms of Neurogenesis, Cell Fate and Maturation, and Degeneration.

Date: December 7, 2016.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–537–9986, *macarthurlh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; HIV/AIDS Innovative Research Applications.

Date: December 7–8, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301–451–8754, *tuoj@nei.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; The Biomedical Technology Research Resource for Macromolecular Modeling and Bioinformatics.

Date: December 7–9, 2016.

Time: 4:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Garden Urbana Champaign Hotel, 1001 W Killarney Street, Urbana, IL 61801.

Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7760, Bethesda, MD 20892, (301) 404–7419, *rosenzweign@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 1, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–26770 Filed 11–3–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Atherosclerosis Risk in Communities Study (National Heart Lung and Blood Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Jacqueline Wright, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892, or call non-toll-free number (301) 435–0384, or Email your request to: *jacqueline.wright@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The Atherosclerosis Risk in Communities Study, 0925–0281, REVISION, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: The ARIC study was initiated in 1985 to examine the major factors contributing to the occurrence of and the trends for cardiovascular diseases among men, women, African Americans and white persons in four U.S. communities: Forsyth County, North Carolina; Jackson, Mississippi; suburbs of Minneapolis, Minnesota; and Washington County, Maryland. The cohort in Jackson is selected to represent only African American residents of the city. The primary objectives of the study are to: (1) Investigate factors associated with both atherosclerosis and clinical cardiovascular diseases and (2) measure occurrence of and trend in coronary heart disease (CHD) and relate them to community levels of risk factors, medical care, and atherosclerosis. Some specific activities for this revision of ARIC are continued telephone follow-up of the ARIC cohort, with twice yearly calls to identify new cardiovascular