Tribes and Tribal organizations must respond if they wish to operate a fully funded program. This paperwork collection activity is set to expire in December, 2016.

Respondents: Tribes and Tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 309 Amended Plan	63	1	120	7,560
45 CFR 309 New Plan	2	1	480	960
Total			600	8,520
Estimated Total Annual Burden Hours			600	8,520

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–26615 Filed 11–3–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Withdrawal of 60-Day Notice of Proposed Information Collection: Unaccompanied Children Case Summary Form

AGENCY: Administration for Children and Families, HHS.

ACTION: Withdrawal: Notice.

SUMMARY: On October 4, 2016 at 81 FR 68420, ACF published a 60 Day Notice of Proposed Information Collection entitled ''Unaccompanied Children Case Summary Form.'' ACF is withdrawing this notice from the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Robert Sargis, Reports Clearance Officer, Office of Planning Research and Evaluation.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–26686 Filed 11–3–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Aging (NIA), National Institute of Mental Health (NIMH), and National Center for Advancing Translational Sciences (NCATS): Cooperative Research and Development Agreement (CRADA) and Licensing Opportunity for Ketamine for the Treatment of Depression and Other Anxiety-Related Disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Aging (NIA), National Institute of Mental Health (NIMH), and National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH), University of Maryland at Baltimore (UMB) and their collaborators are seeking Cooperative Research and Development Agreement (CRADA) partners to collaborate in the preclinical and clinical development of ketamine metabolite (2R, 6R-HNK) for the treatment of depression and other anxiety-related disorders.

DATES: 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.

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: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301–217–9197, Fax: 301–217–5736, or email *NCATSPartnerships@mail.nih.gov.* A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: As per the Anxiety and Depression Association of America, Major depressive disorder affects 14.8 million people in America, including children, adults, and the elderly. A number of therapies currently exist to treat depression, although they suffer drawbacks such as requiring weeks to take action. One particular therapy includes the approved drug, ketamine, which has demonstrated robust and acute antidepressant activity. However, its efficacy is bridled with significant disadvantages including its addictive potential and its dissociative activities. This is the case even when administered at low doses, which limits the potential widespread use of ketamine as an antidepressant medication.

In order to improve the treatment of depression, it is important to explore the mechanism by which ketamine exerts its antidepressant effects. That is precisely what the NIH and UMB scientists and collaborators are investigating, and have found that the metabolism of ketamine is critical to its antidepressant effects, and that the (2R,6R)-2-amino-2-(2-chlorophenyl)-6-hydroxycyclohexanone ((2R,6R)-hydroxynorketamine (HNK)) metabolite, reversed depression-like behaviors in mice without triggering anesthetic, dissociative, or addictive side effects associated with ketamine. Specifically, the researchers found that the

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