

maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search

data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden

hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Opioid Program Grant Performance Measures	10	1	10	11	110
Total	10	10	110

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–09668 Filed 5–4–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel PHS, 2017–1 NIAID Topic 43 (Adjuvant Development).

Date: May 30, 2018.

Time: 10:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–507–9685, thomas.conway@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,

Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 2, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–09659 Filed 5–4–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Antibodies Against TL1A, a TNF-Family Cytokine, for the Treatment and Diagnosis of Crohn's Disease, Ulcerative Colitis, Asthma, Psoriasis and Biliary Cirrhosis

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute (“NHLBI”), an institute of the National Institutes of Health, an agency within the Department of Health and Human Services, is contemplating the grant of an exclusive patent license to commercialize the invention(s) embodied in the intellectual property estate stated in the Summary Information section of this notice to Precision IBD, Inc., located in San Diego, California, and incorporated under the laws of Delaware.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development on or before May 22, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Cristina Thalhammer-Reyero, Ph.D., MBA, Senior Licensing and Patenting Manager, NHLBI Office of Technology

Transfer and Development, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; Telephone: +1–301–435–4507; Fax: +1–301–594–3080; Email: thalhamc@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

U.S. Provisional Patent Application No. 61/488,671, filed May 20, 2011; PCT Application. No. PCT/US2012/028926, filed March 13, 2012; U.S. Patent No. 9,068,003, issued June 30, 2015; U.S. Patent No. 9,896,511, issued February 20, 2018; and U.S. Patent Application No. 15/872,592, filed January 16, 2018, “Antibodies Against TL1A, a TNF-Family Cytokine, for the Treatment and Diagnosis of Autoimmune Inflammatory Diseases”, NIH Reference No. E–073–2011/0,1,2.

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: “Development and commercialization of antibodies against TL1A for the treatment and diagnosis of Crohn's Disease, Ulcerative Colitis, Asthma, Psoriasis and Biliary Cirrhosis”

The subject technology is based on the use of antibodies against TL1A, a TNF-Family cytokine, for the treatment and diagnosis of autoimmune inflammatory diseases. Autoimmune inflammatory diseases occur in greater than five percent of the U.S. population. Treatments generally include immunosuppressants or anti-inflammatory drugs, which can have serious side effects. Recently, more specific immunomodulatory therapies such as TNF-alpha antagonists have been developed. In experiments with

mice, NIAMS inventors have shown that the interaction between the TNF family ligand TL1A with its receptor, DR3, is critical for development of disease in asthma, inflammatory bowel disease and multiple sclerosis. They have also developed anti-TL1A antibodies that prevent disease in mouse models of rheumatoid arthritis and inflammatory bowel disease. This invention describes anti-human TL1A monoclonal antibodies that may be useful for the development of diagnostics and therapeutics for autoimmune inflammatory diseases, as well as methods of treating such diseases by blocking the interaction between TL1A and DR3 by the described antibodies. This specific immunomodulatory effect provides potential for potent therapy without inducing global immunosuppression.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI Office of Technology Transfer and Development 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.

The public may file comments or objections in response to this Notice. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 27, 2018.

Cristina Thalhammer-Reyero,

*Senior Licensing and Patenting Manager,
Office of Technology Transfer and
Development, National Heart, Lung, and
Blood Institute.*

[FR Doc. 2018-09654 Filed 5-4-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used for Identifying Potential Developmental Toxicants

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for identifying potential developmental toxicants. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring.

DATES: Receipt of information: Deadline for receipt of information is June 15, 2018.

ADDRESSES: Data and information should be submitted electronically to niceatm@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Deputy Director, NICEATM; email: nicole.kleinstreuer@nih.gov; telephone: (984) 287-3150.

SUPPLEMENTARY INFORMATION:

Background: NICEATM fosters the evaluation and promotion of alternative test methods for regulatory use and supports efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants that replace, reduce, or refine animal use. Testing a chemical's potential to cause developmental toxicity is required by multiple federal agencies for regulatory and other decision contexts, and can use large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to identify potential developmental toxicants. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo developmental toxicity test methods currently used by federal agencies for regulatory and other decision contexts. NICEATM also requests available data from in vivo developmental studies, human or animal studies, or accidental human exposures, using the same chemicals used to evaluate the alternative developmental toxicity test methods.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is June 15, 2018. Responses to this notice will be posted at: <https://ntp.niehs.nih.gov/go/dev-nonanimal>. Persons submitting responses will be identified on the web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285j-3) provides authority for ICCVAM and NICEATM involvement in activities relevant to the development of alternative test methods. Information about NICEATM and ICCVAM can be found at <http://ntp.niehs.nih.gov/go/niceatm> and <http://ntp.niehs.nih.gov/go/iccvam>.

Dated: April 27, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018-09661 Filed 5-4-18; 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, 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