

receive due consideration, the prospective trainee is encouraged to complete all relevant fields. The information is for internal use to make decisions about prospective fellows and

students that could benefit from the DCEG program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total

estimated annualized burden hours are 175.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Summer Students	300	1	20/60	100
Full-time Fellows	150	1	30/60	75

Dated: April 3, 2014.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program (NIAID)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on 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.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Lyndi Lahl, RN, MS, Office for Policy in Clinical Research Operations, DAIDS, NIAID, 6700B Rockledge Drive, Room 4254, Bethesda, MD 20852, or call non-toll-free number 301-435-3756, or Email your request, including your address to: Lynda.Lahl@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

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

Proposed Collection: Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program, 0925-New, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a new data collection to assess the CEPI program's progression to fulfillment of its program goals and will assess whether the CEPI program is implemented and functioning as intended. The program goals for CEPI are: (1) Awareness & Accessibility—The target populations (DAIDS Staff, extramural researchers, external stakeholders) are aware of the DAIDS Critical Events (CE) policy and manual and associated documents and whether the policy and associated documents are

readily accessible.; (2)

Understandability—The Critical Events policy and manual clearly articulate DAIDS expectations for CE policy implementation by the target populations. The CE policy and manual should establish a common base of understanding and promote positive attitudes towards event reporting; and (3) **Applicability**—Target populations are able to correctly identify which Critical Events have occurred at their sites and are able to apply the CE policy and manual to their events.

Findings will provide data to inform DAIDS and Protection of Participants, Evaluation and Policy (ProPEP) leadership regarding further policy deployment decisions. Information collected will be used to determine how effectively the CEPI Program meets extramural researchers' needs. By assessing the CEPI Program, DAIDS will determine how successfully it is reaching its goals—to facilitate and improve the quality of clinical research conducted within the division. In addition, the CEPI Program assessment will determine whether previously recommended improvements included in the DPIP assessment were successfully incorporated into the policy rollout process. The results may be used as a model for policy development to facilitate compliance in reporting certain incidents and implementation in other National Institutes of Health (NIH) Institutes and Centers (ICs) and will be shared with all interested divisions and institutes within the NIH. There are no plans to share this information with the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 386.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Data collection	Number of respondents	Number of responses per respondent	Average time per response	Total annual burden hours
DAIDS Staff, ER/ES	Survey	500	1	30/60	250
	Focus Group-IC Review	81	1	10/60	14
	Focus Group	81	1	90/60	122

Dated: April 3, 2014.

Brandie Taylor,

Project Clearance Liaison, NIAID, NIH.

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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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing 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.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Monoclonal Antibody Fragments for Targeting Therapeutics to Growth Plate Cartilage

Description of Technology: A child's growth is dependent on the proper functioning of the growth plate, a specialized cartilage structure located at the ends of long bones and within the vertebrae. The primary function of the growth plate is to generate new cartilage, which is then converted into bone tissue and results in the lengthening of bones. Current

treatments for severe short stature and skeletal growth disorders are limited. Recombinant human growth hormone (GH) is typically used but the results are less than optimal and have potential adverse effects. The instant invention discloses that monoclonal antibodies that bind to matrilin-3, a protein specifically expressed in cartilage tissue, could be used for treating or inhibiting growth plate disorders, such as a skeletal dysplasia or short stature.

Potential Commercial Applications: A new treatment option for growth plate disorders, such as skeletal dysplasia or short stature.

Competitive Advantages: Avoidance of the risks associated with systemic treatment using growth hormone, such as increased intracranial pressure, slipped capital femoral epiphysis, insulin resistance, and possibly type II diabetes.

Development Stage:

- Early-stage.
- *In vitro* data available.

Inventors: Jeffrey Baron (NICHD), Sao Fong (Crystal) Cheung (NICHD), Chun Kin Julian Lui (NICHD), Dimitar S. Dimitrov (NCI), Zhongyu Zhu (NCI).

Intellectual Property: HHS Reference No. E-003-2014/0—US Application No. 61/927,904 filed 15 Jan 2014.

Licensing Contact: Betty B. Tong, Ph.D.; 301-594-6565; tongb@mail.nih.gov.

Collaborative Research Opportunity: The Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Cancer Institute are seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize treatment of skeletal disorders and short stature to increase growth using targeting antibodies. For collaboration opportunities, please contact Joseph Conrad III, Ph.D. at jmconrad@mail.nih.gov.

Human Antibodies Against Middle East Respiratory Syndrome Coronavirus

Description of Technology: No effective therapeutics or vaccines are available against Middle East Respiratory Syndrome Coronavirus (MERS-CoV). This technology is for

human antibodies targeting MERS-CoV. Certain of these antibodies bind with epitopes of the MERS-CoV receptor binding domain (RBD) of MERS-CoV spike (S) protein with high affinity and are capable of neutralized the virus in a pseudovirus assay. The MERS-CoV-S protein is believed to be required for binding and virus entry during MERS-CoV infection. The human to human aspect of transmission and the high mortality rate associated with MERS-CoV infection have raised concerns over the potential for a future MERS-CoV pandemic and emphasized the need for development of effective therapeutics and vaccines. The antibodies of this technology represent candidate antibody-based therapeutics for treatment of MERS-CoV infection.

Potential Commercial Applications: Antibody-based therapeutics for treatment of MERS-CoV infection.

Competitive Advantages:

- No vaccine or other biologic therapy is available.
- High binding (sub-nanomolar) affinity.
- Relative safety and long half-lives.

Development Stage:

- Early-stage.
- *In vitro* data available.

Inventors: Dimitar Dimitrov (NCI), Tianlei Ying (NCI), Tina Yu (NCI), Kwok Yuen (University of Hong Kong).

Publications:

1. Zaki AM, et al. Isolation of a novel coronavirus from a man with pneumonia in Saudi Arabia. *N Engl J Med.* 2012 Nov 8;367(19):1814-20. [PMID 23075143]
2. Zhu Z, et al. Exceptionally potent cross-reactive neutralization of Nipah and Hendra viruses by a human monoclonal antibody. *J Infect Dis.* 2008 Mar 15;197(6):846-53. [PMID 18271743]
3. Zhu Z, et al. Potent cross-reactive neutralization of SARS coronavirus isolates by human monoclonal antibodies. *Proc Natl Acad Sci U S A.* 2007 Jul 17;104(29):12123-8. [PMID 17620608]

Intellectual Property: HHS Reference No. E-002-2014/0—U.S. Patent Application No. 61/892,750 filed 18 Oct 2013.