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:** NIH NeuroBioBank Tissue Access Request Form, 0925–0723, Expiration date 07/31/2018, EXTENSION, National Institute of Mental Health, National Institutes of Health (NIMH).

**Need and Use of Information Collection:** This request serves as notice that the National Institute of Mental Health plans to continue supporting the research community studying neurological, developmental, and psychiatric disorders by coordinating access to human post-mortem brain tissue and related biospecimens stored by our federation of networked brain and tissue repositories known as the NIH NeuroBioBank. To facilitate this process, researchers wishing to obtain brain tissue and biospecimens stored by the NIH NeuroBioBank must continue completing the NIH NeuroBioBank Tissue Access Request Form. The primary use of the information collected by this instrument is to document, track, monitor, and evaluate the appropriate use of the NIH NeuroBioBank resources, as well as to notify stakeholders of updates, corrections or changes to the system.

OMB approval is requested for 3 years. There are no costs to respondents’ other than their time. The total estimated annualized burden hours are 56.

**ESTIMATED ANNUALIZED BURDEN HOURS**

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<th>Instrument type</th>
<th>Type of respondents</th>
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<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
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**SUPPLEMENTARY INFORMATION:**

**Technology description follows.**

**Stabilized Influenza Hemagglutinin Stem Region Trimers and Uses Thereof**

Description of Technology

An effective universal influenza vaccine would eliminate the uncertain and costly process of seasonal influenza vaccine development each year. Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) are developing immunogens which elicit neutralizing antibodies to the highly conserved stem region of the influenza viral protein hemagglutinin. By targeting this highly conserved region, which is nearly identical in various strains of influenza virus, these immunogens could train the immune system to defend against a wide variety of influenza strains including pandemic strains derived from animal reservoirs.

This vaccine candidate employs a protein nanoparticle platform to display portions of the highly conserved stem region of the group 1 hemagglutinin (HA) viral surface protein in its native, trimeric conformation. Animal studies have shown that the HA stem region trimers displayed on a nanoparticle are more immunogenic compared to HA stem region trimers alone. Immunization of mice and ferrets with an H1N1 nanoparticle HA stem immunogen conferred protection from a lethal dose of H3N1 virus. NIAID is continuing development of these vaccine candidates through animal studies and moving toward clinical evaluation.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

**Potential Commercial Applications**

- Universal influenza vaccine

**Competitive Advantages**

- Nucleic acid or recombinant protein-based vaccine

- Increased ease of production relative to current seasonal influenza vaccines

**Development Stage**

- Preclinical, animal data available

**Inventors:** John R. Mascola, Jeffrey C. Boyington, Hadi M. Yassine, Peter D. Kwong, Barney S. Graham, Masaru Kanekiyo (all from NIAID).


**Intellectual Property:** HHS Reference Number E–066–2014 includes U.S. Patent Application No. 15/13,265 filed November 22, 2016 (Pending); Canada Patent Application No. 2,950,085 filed November 22, 2016 (Pending); China Patent Application No. 201580041202.3 filed January 24, 2017 (Pending); Europe Patent Application No. 15727824.3 filed December 23, 2016 (Pending); India...
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

Cooperative Research and Development Agreement: Safe Parameters for Ice Operations

AGENCY: Coast Guard, DHS.

ACTION: Notice of intent; request for comments.

SUMMARY: The Coast Guard is announcing its intent to enter into a Cooperative Research and Development Agreement (CRADA) with W.L. GORE and Associates Inc. (GORE) to conduct insulation value testing for the Coast Guard’s Maritime Cold Weather Suit System (MWCSS) in the air instead of the water, which the system was designed for. While the Coast Guard is currently considering partnering with GORE, we are soliciting public comment on the possible nature of and participation of other parties in the proposed CRADA. In addition, the Coast Guard also invites other potential non-Federal participants, who have the interest and capability to bring similar contributions to this type of research, to consider submitting proposals for consideration in similar CRADAs.

DATES: Comments must be submitted to the online docket via http://www.regulations.gov on or before May 21, 2018.

Addresses of proposals regarding future CRADAs must reach the Coast Guard (see FOR FURTHER INFORMATION CONTACT) on or before May 21, 2018.

ADDRESSES: Submit comments online at http://www.regulations.gov following website instructions.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice or wish to submit proposals for future CRADAs, contact LT Ryan Huebner, Project Official, Surface Branch, U.S. Coast Guard Research and Development Center, 1 Chelsea Street, New London, CT 06320, telephone 860–271–2815, email Ryan.P.Huebner@uscg.mil.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We request public comments on this notice. Although we do not plan to respond to comments in the Federal Register we will respond directly to commenters and may modify our proposal in light of comments.

Comments should be marked with docket number USCG–2018–0185 and should provide a reason for each suggestion or recommendation. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the Federal Register Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008). We also accept anonymous comments.

We encourage you to submit comments through the Federal eRulemaking Portal at http://www.regulations.gov. If your material cannot be submitted using http://www.regulations.gov, contact the Coast Guard (see FOR FURTHER INFORMATION CONTACT). Documents mentioned in this notice, and all public comments, are in our online docket at http://www.regulations.gov and can be viewed by following that website’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

If desired, submit detailed proposals for future CRADAs directly to the Coast Guard (see FOR FURTHER INFORMATION CONTACT).

Discussion

CRADAs are authorized under 15 U.S.C. 3710(a). A CRADA promotes the transfer of technology to the private sector for commercial use, as well as specified research or development efforts that are consistent with the mission of the Federal parties to the CRADA. The Federal party or parties agree with one or more non-Federal parties to share research resources, but the Federal party does not contribute funding. CRADAs are not procurement contracts. Care is taken to ensure that CRADAs are not used to circumvent the contracting process. CRADAs have a specific purpose and should not be confused with procurement contracts, grants, and other type of agreements.

Under the proposed CRADA, the R&D Center will collaborate with one non-Federal participant. Together, the R&D Center and the non-Federal participant will conduct thermo conductive tests on the Coast Guard’s MWCSS in various environmental scenarios to determine the system’s insulation properties to be used to create safe parameters for personnel wearing the MWCSS during Ice Rescue missions.

We anticipate that the Coast Guard’s contributions under the proposed CRADA will include the following:

(1) Provide appropriate staff with pertinent expertise to take the lead in accomplishing the required tasks;
(2) Provide information regarding the ensemble items and parameters needed for creating the test plan;
(3) Provide all support resources, including travel, for Coast Guard staff that supports this CRADA;
(4) Obtain, transport and provide all of the ensemble items to be used during the testing;
(5) Provide personnel support to non-Federal participant to assist with setting up and execute testing in accordance with the agreed upon test plan;
(6) Work with non-Federal participant to develop a Final Report, which will document the methodologies, findings, conclusions, and recommendations of this CRADA work.

We anticipate that the non-Federal participants’ contributions under the proposed CRADA will include the following:

(1) Provide appropriate staff with pertinent expertise to support the above mentioned tasks;
(2) Provide all necessary facility resources needed to conduct insulation value testing;
(3) Provide technical approach for the test plan;
(4) Lead the testing runs of the Coast Guard’s MWCSS in accordance with the agreed upon test plan;
(5) Provide test data upon completion of testing.

The Coast Guard reserves the right to select for CRADA participants all, some,