

registration, obtain accreditations for continuing education units as appropriate and handle all logistical support leading up to and at the forum;

- Provide travel expenses for additional academic faculty;
- Duplicate all forum materials and prepare participant notebook as appropriate;
- Distribute and collect from speakers signed authorization forms (wording and format provided by OHRP) that permit OHRP to retain and re-use speakers' presentations as well as any video recordings of the presentations obtained in the course of the Forum for educational purposes;
- Provide OHRP with copies of the speakers' slide presentations (slides and any associated video recordings), as well as any video-recordings of conference presentations obtained in the course of the Forum, no later than 4 months after the RCF;
- Produce and share with OHRP a summary and evaluation report as well as the list of participants with their email information.

### 3. Registration Fees and Other Charges

[Co-sponsor] has established a tentative registration fee schedule, \$[Amount] for the 1-day conference; \$[Amount] for the 1-day workshop; and \$[Amount] when registering for both conference and workshop. These registration fees are no higher than necessary for [co-sponsor] to recover its share of the costs for co-sponsoring this event and may be lowered, as the arrangements for the forum event are made and expenses are incurred.

HHS staff will be serving as faculty members and resource people. There is no attendance fee for HHS staff.

[Co-sponsor] does not intend to sell educational materials pertaining to this event.

### 4. Independently Sponsored Portions of Event

[Co-sponsor] may decide to independently provide food for lunch and/or at breaks for the Workshop/Event attendees as a discrete portion of the event. The workshop/event agenda will indicate that this portion of the event is independently sponsored by [co-sponsor]. OHRP staff and resources will not be used to develop, promote, or otherwise support this portion of the event.

### 5. Fund Raising

[Co-sponsor] will make clear in any solicitation for funds to cover its share of the event costs that it, not OHRP, is asking for the funds. [Co-sponsor] will not imply that OHRP endorses any fund

raising activities in connection with the Forum. [Co-sponsor] will make clear to donors that any gift will go solely toward defraying the sponsorship expenses of the event, not to OHRP.

### 6. Promotional Activity

[Co-sponsor] will not use the event primarily as a vehicle to sell or promote products or services. [Co-sponsor] will ensure that any incidental promotional activity does not imply that OHRP endorses any of its products or services. [Co-sponsor] will make reasonable efforts, subject to OHRP review, to segregate any incidental promotional activity from the main activities of the event.

### 7. Event Publicity and Endorsements

[Co-sponsor] will not use the name of OHRP or any of its components, except in factual publicity for the specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Such factual publicity shall not imply that the involvement of OHRP in the event serves as an endorsement of the general policies, activities, or products of [co-sponsor]; where confusion could result, publicity should be accompanied by a disclaimer to the effect that no endorsement by OHRP is intended. [Co-sponsor] will clearly state on the agenda that OHRP did not provide funding for the breaks and lunch at the forum. [Co-sponsor] will state on the agenda which organization provided the funding for the breaks and lunch at the forum. [Co-sponsor] will clear all publicity materials for the event with OHRP to ensure compliance with this paragraph.

### 8. Records

Records concerning the event shall account fully and accurately for the financial commitments and expenditures of OHRP and [co-sponsor]. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

### 9. Public Availability

This co-sponsorship agreement, as well as the financial records described in paragraph 8, shall be publicly available upon request.

### 10. Co-sponsorship Guidance

OHRP and [co-sponsor] will abide by the legal memorandum of August 8, 2002, "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official.

*Evaluation Criteria:* After engaging in exploratory discussions with potential co-sponsors, OHRP will select the co-

sponsor or co-sponsors that would best fulfill OHRP's mission. Evaluation may include the following criteria:

- Qualifications and capability to fulfill co-sponsorship responsibilities;
- Suitability of the location of the proposed event in terms of the overall geographical distribution of OHRP-RCFs;
- Interests in human research protections that complement and promote OHRP's interests and agenda;
- Creativity and innovations related to the human research protections topics proposed to cover;
- Creativity in enhancing the conference, including ideas for improving the event based on prior RCFs;
- Potential for reaching, generating, and engaging attendees from diverse key stakeholders;
- Availability and description of facilities needed to support the RCF;
- Availability of administrative expertise, experience, and support (including accounting and event management) for the logistics of hosting events of a similar scale.

**FOR FURTHER INFORMATION CONTACT:** OHRP-EDU@HHS.GOV or call OHRP's Division of Education and Development (DED) at 240-453-6900.

Dated: June 29, 2016.

**Karen DeSalvo,**

*Acting Assistant Secretary for Health.*

[FR Doc. 2016-16004 Filed 7-5-16; 8:45 am]

**BILLING CODE 4150-36-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Request for Public Comment: 60-Day Information Collection: Application for Participation in the IHS Scholarship Program

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice and request for comments. Request for extension of approval.

**SUMMARY:** In compliance the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "Application for Participation in the IHS Scholarship Program," Office of Management and Budget (OMB) Control No. 0917-0006. IHS is requesting OMB to approve an extension for this collection, which expires on September 30, 2016.

**DATES:** *Comment Due Date:* September 6, 2016. Your comments regarding this information collection are best assured

of having full effect if received within 60 days of the date of this publication.

**ADDRESSES:** Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Mr. Robert Pittman by one of the following methods:

- *Mail:* Robert E. Pittman, BPharm, MPH, Acting Chief, Scholarship Branch Director, Division of Health Professions Support, Indian Health Service, 5600 Fishers Lane, Mail Stop: OHR 11E53A, Rockville, MD 20857.
- *Phone:* (301) 443-6197.
- *Email:* Robert.Pittman@ihs.gov.
- *Fax:* 301-443-6048.

**SUPPLEMENTARY INFORMATION:** This previously approved information collection project was last published in the **Federal Register** (78 FR 49532) on August 14, 2013 and allowed 30 days for public comment. No public

comment was received in response to the notice. The purpose of this notice is to allow 60 days for public comment. A copy of the supporting statement is available at [www.regulations.gov](http://www.regulations.gov) (see Docket ID IHS-2016-0005).

*Information Collection: Title:* “Application for Participation in the IHS Scholarship Program,” OMB Control No. 0917-0006. *Type of Information Collection Request:* Extension of the currently approved information collection “Application for Participation in the IHS Scholarship Program,” OMB Control No. 0917-0006. *Form Number(s):* IHS-856-3, IHS-856-5 through 856-19, IHS-856-21 through 856-24, IHS-817, and IHS-818 are retained for use by the IHS Scholarship Program (IHSSP) as part of this current information collection request. Reporting forms are found on the IHS Web site at [www.ihs.gov/scholarship](http://www.ihs.gov/scholarship). *Need and Use of Information Collection:*

The IHS Scholarship Branch needs this information for program administration and uses the information to: solicit, process, and award IHS Pre-graduate, Preparatory, and/or Health Professions Scholarship recipients; monitor the academic performance of recipients; and to place recipients at payback sites. The IHSSP application is electronically available on the internet at the IHS Web site at: <https://www.ihs.gov/scholarship/applynow/>. *Affected Public:* Individuals, not-for-profit institutions and State, local or Tribal Governments. *Type of Respondents:* Students pursuing health care professions.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hours.

Data collection instrument(s)	Number of respondents	Responses per respondent	Total annual response	Burden hour per response*	Annual burden hours
Faculty/Employer Evaluation (IHS-856-3)	1,500	2	3,000	0.42 (25 min)	1,250
Delinquent Federal Debt (IHS-856-5)	1,500	1	1,500	0.13 (8 min)	200
Course Curriculum Verification (IHS-856-6)	1,500	1	1,500	0.70 (42 min)	1,050
Verification of Acceptance or Decline of Award (IHS-856-7)	350	1	350	0.13 (8 min)	47
Recipient's Initial Program Progress Report (IHS-856-8)	1,200	1	1,200	0.13 (8 min)	160
Notification of Academic Problem (IHS-856-9)	50	1	50	0.13 (8 min)	7
Change of Status (IHS-856-10)	50	1	50	.045 (25 min)	21
Request for Approval of Deferment (IHS-856-11)	20	1	20	0.13 (8 min)	3
Preferred Placement (IHS-856-12)	150	1	150	0.50 (30 min)	75
Notice of Impending Graduation (IHS-856-13)	120	1	120	0.17 (10 min)	20
Notification of Deferment Program (IHS-856-14)	20	1	20	0.13 (8 min)	3
Placement Update (IHS-856-15)	120	1	120	0.18 (11 min)	22
Annual Status Report (IHS-856-16)	200	1	200	0.25 (15 min)	50
Extern Site Preference Request (IHS-856-17)	300	1	300	0.13 (8 min)	40
Request for Extern Travel Reimbursement (IHS-856-18)	150	1	150	0.10 (6 min)	15
Lost Stipend Payment (IHS-856-19)	50	1	50	0.13 (8 min)	7
Summer School Request (IHS-856-21)	100	1	100	0.10 (6 min)	10
Change of Name or Address (IHS-856-22)	20	1	20	0.13 (8 min)	3
Request for Credit Validation (IHS-856-23)	30	1	30	0.10 (6 min)	3
Faculty/Advisor Evaluation (IHS-856-24)	1,500	2	3,000	0.42 (25 min)	1,250
Scholarship Program Agreement (IHS-817)	175	1	175	0.16 (10 min)	29
Health Professions Contract (IHS-818)	225	1	225	0.16 (10 min)	38
<b>Total</b>			<b>12,580</b>		<b>4,303</b>

\* For ease of understanding, burden hours are also provided in actual minutes.

There are no direct costs to respondents other than their time to voluntarily complete the forms and submit them for consideration. The estimated cost in time to respondents, as a group, is \$46,386 [4,303 burden hours × \$10.78 per hour (2016 GS-3 hourly base pay rate)]. This total dollar amount is based upon the number of burden hours per data collection instrument, rounded to the nearest dollar.

*Requests for Comments:* Your written comments and/or suggestions are invited on one or more of the following points:

- (a) Whether the information collection activity is necessary to carry out an agency function;
- (b) whether the agency processes the information collected in a useful and timely fashion;
- (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information);
- (d) whether the methodology and assumptions used to determine the estimates are logical;

(e) ways to enhance the quality, utility, and clarity of the information being collected; and

(f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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

Dated: June 24, 2016.

**Elizabeth A. Fowler,**

*Deputy Director for Management Operations,  
Indian Health Service.*

[FR Doc. 2016-16008 Filed 7-5-16; 8:45 am]

**BILLING CODE 4165-16-P**

## 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 invention listed below is co-owned by an agency of the U.S. Government and is available for licensing and/or co-development 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 and/or co-development.

**ADDRESSES:** Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

**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. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

#### SUPPLEMENTARY INFORMATION:

Technology description follows.

*Title of Invention:* Shark Antibodies that Target Tumor and Viral Antigens.

*Description of Technology:* Shark V-NAR (Variable New Antigen Receptor) antibodies are an emerging class of therapeutic candidates. As single domain (heavy chain) antibodies with an extensive antigen-binding repertoire, shark V-NAR antibodies may provide advantages over traditional antibodies. Specifically, the smaller size of shark V-NAR antibodies may provide increased solubility, thermal stability, refolding capacity, and the ability to recognize

epitopes that are sterically hindered from recognition by larger antibodies, but without loss of specificity in antigen-binding.

Researchers at the National Cancer Institute's Laboratory of Molecular Biology (NCI LMB) have developed an immunological platform that includes the development of a shark V-NAR antibody phage display library, isolation of specific antibodies that bind to several tumor and viral antigens from the library, and the development of the specific antibodies for treatment of cancer or viral infection. Specific antibody targets for binders include tumor-specific antigens (GPC3 [*Clone F1*], PD1 [*Clone A1*], HER2 [*Clones A6/A7*]), and viral antigens (MERS [*Clones A3, A7, A8, B4, and B5*] and SARS [*Clone O1*]).

Anti-glypican 3 (GPC3) V-NAR, Clone F1, is an antibody of immediate interest since it has already shown specific binding to GPC3-expressing tumor cells *in vitro*. Thus, anti-GPC3 V-NAR represents a viable candidate for development of an antibody-toxin/drug conjugate (ADC and immunotoxin), a bispecific antibody or a chimeric antigen receptor (CAR) against GPC3-expressing tumor cells.

#### *Potential Commercial Applications:*

- Therapeutic Uses
  - Use as unconjugated antibodies
  - Use as targeting moieties for immunoconjugates such as CARs, ADCs, Immunoconjugates, bispecific antibodies, etc.
- Diagnostic agent for detecting and monitoring target-expressing malignancies

#### *Value Proposition:*

- Potential to be first to market with high specificity and binding to targets resulting in less non-specific cell killing, therefore fewer potential side-effects for the patient
- Small size of antibodies enhances stability, solubility, and target recognition

#### *Development Stage:*

- *In-vitro* data—Shark/Human anti-GPC3 chimera can bind to GPC3-positive tumor cells
  - *In-vivo* testing
- Inventor(s):* Mitchell Ho (NCI), *et al.*  
*Intellectual Property:* US Provisional Application 62/334,194 (HHS Reference No. E-113-2016/0-US-01) filed May 10, 2016 entitled "Variable New Antigen Receptor (VNAR) Antibodies and Antibody Conjugates Targeting Tumor and Viral Antigens".

#### *Collaboration Opportunity:*

Researchers at the NCI seek parties interested in licensing or co-developing shark V-NAR antibodies and/or conjugates for cancer therapeutics and/or diagnostics.

*Contact Information:* Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

Dated: June 28, 2016.

**John D. Hewes,**

*Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2016-15898 Filed 7-5-16; 8:45 am]

**BILLING CODE 4140-01-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 (5 U.S.C. App.), 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 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:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Opportunities for Collaborative Research at the NIH Clinical Center (U01).

*Date:* August 2, 2016.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892-9823, (240) 669-5023, [fdesilva@niaid.nih.gov](mailto:fdesilva@niaid.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)