

evaluation nor programmatic purposes. HRSA also added questions to the 3Ps Information Form to allow the Form to be used as an all-inclusive data collection instrument for MCHB and Healthy Start grantees. The additional questions extend and refine previously approved content, allowing for the collection of more granular and/or in-depth information on existing topics. Adding these questions allows Healthy Start grantees to better assess risk, identify needed services, provide appropriate follow-up activities to program participants, and improve overall service delivery and quality.

**Need and Proposed Use of the Information:** The purpose of the data collection instruments is to obtain consistent information across all grantees about Healthy Start and its outcomes. The data will be used to: (1) Conduct ongoing performance monitoring of the program; (2) provide credible and rigorous evidence of

program effect on outcomes; (3) assess the relative contribution of the five program approaches to individual and community-level outcomes; (4) meet program needs for accountability, programmatic decision-making, and ongoing quality assurance; and (5) strengthen the evidence-base, and identify best and promising practices for the program to support sustainability, replication, and dissemination of the program.

**Likely Respondents:** Respondents include project directors and staff for the National Healthy Start Program Survey; representatives from partner organizations for the Community Action Network Survey; program staff, providers, and partners for the Healthy Start Site Visit Protocol; and program participants for the Healthy Start Participant Focus Group Protocol. Respondents for the redesigned 3Ps Information Form (*i.e.*, (1) Demographic Intake; (2) Pregnancy Status/History; (3)

Preconception; (4) Prenatal; (5) Postpartum; and (6) Interconception/Parenting) are pregnant women and women of reproductive age who are served by the Healthy Start Program.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and 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
3Ps Information Form:					
1. Demographic Intake Form .....	* + 40,675	1	40,675	0.08	3,254
2. Pregnancy Status/History .....	40,675	1	40,675	0.17	6,915
3. Preconception .....	* + 20,337	1	20,337	1.00	20,337
4. Prenatal .....	20,337	1	20,337	1.00	20,337
5. Postpartum .....	20,337	1	20,337	1.00	20,337
6. Interconception/Parenting .....	20,337	1	20,337	1.00	20,337
National Healthy Start Program Web Survey .....	+ 100	1	100	2.00	200
CAN member Web Survey .....	+ 225	1	225	0.75	169
Healthy Start Site Visit Protocol .....	+ 15	1	15	6.00	90
Healthy Start Participant Focus Group Protocol .....	+ 180	1	180	1.00	180
<b>Total .....</b>	<b>61,532</b>	<b>.....</b>	<b>61,532</b>	<b>.....</b>	<b>92,156</b>

\* The same individuals (40,675) complete the Demographic Intake and Pregnancy Status/History forms, and a subset of these same individuals (20,337) also complete the Preconception, Prenatal, Postpartum, and Interconception/Parenting forms for total of 61,532 respondents and responses.

+ These are the numbers included in the total respondent count.

**Jason E. Bennett,**  
 Director, Division of the Executive Secretariat.  
 [FR Doc. 2016-21889 Filed 9-12-16; 8:45 am]  
 BILLING CODE 4165-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Office of the Director Notice of Charter Renewal**

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102-3.65(a), notice is hereby given that the Charter for the Fogarty International Center Advisory Board

was renewed for an additional two-year period on August 31, 2016.

It is determined that the Fogarty International Center Advisory Board is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or [spaethj@od.nih.gov](mailto:spaethj@od.nih.gov).

Dated: September 6, 2016.

**Jennifer Spaeth,**  
 Director, Office of Federal Advisory Committee Policy.  
 [FR Doc. 2016-21899 Filed 9-12-16; 8:45 am]  
 BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings**

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 meetings.

The meetings 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Cell Replacement Technology for Type 1 Diabetes (SBIR).

*Date:* October 4, 2016.

*Time:* 12:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, [tatham@mail.nih.gov](mailto:tatham@mail.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary Studies (R01).

*Date:* October 27, 2016.

*Time:* 11:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Jason D. Hoffert, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7343, 6707 Democracy Boulevard, Bethesda, MD 20817, 301-496-9010, [hoffertj@nidk.nih.gov](mailto:hoffertj@nidk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 7, 2016.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-21895 Filed 9-12-16; 8:45 am]

**BILLING CODE 4140-01-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 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:* Analogues of Withanolide E Sensitize Cancer Cells to Apoptosis.

*Keywords:* TRAIL, TLR3, apoptosis, immunotherapy, tumor necrosis factor, TNF.

*Description of Technology:* The tumor necrosis factor (TNF)-related apoptosis-inducing ligand (TRAIL) protein has been a target of interest in cancer therapy because it plays a large role in inducing cell apoptosis in cancer cells but not in normal cells. Although TRAIL has been reported to successfully target certain tumor cells which are resistant to traditional chemotherapy or radiation, TRAIL resistance has also been widely observed. Similarly, Toll-like receptor (TLR) 3 ligands such as poly I:C have also been reported to promote apoptosis in certain cancer cells, though the apoptotic signaling in

most cancer cells was weak and was only significant following longer term incubations. Thus, there is a need to develop compounds that can sensitize cancer cells to apoptosis inducing ligands, such as poly I:C and TRAIL.

In collaboration with the University of Arizona, NCI investigators have discovered a series of compounds in the withanolide family that synergistically enhance the response of cancer cells to treatment with an apoptosis-inducing ligand. The compounds each show a 4- to 10-fold increase in potency compared to withanolide E alone in promoting death ligand-mediated cancer cell death. One biotinylated analogue in particular is at least 15-fold more potent than withanolide E in promoting apoptosis in human melanoma cells when used in combination with either poly I:C or TRAIL. A selection of active compounds were tested in murine xenograft models of human melanoma and showed decreased tumor growth and tumor regression.

**Potential Commercial Applications**

- Potential therapeutic for the treatment of cancer either alone or in combination with an apoptosis inducing agent such as TRAIL receptor or TLR 3 agonists by directly promoting tumor cell apoptosis.
- Possible indirect enhancement of cancer immunotherapy due to release of cancer cell antigens in the presence of the powerful immune-adjutant effects of TLR3 agonists.

**Value Proposition**

- Withanolide E derivatives enhance the anti-cancer activity of known apoptosis inducing ligands such as TRAIL or poly I:C and may be used to enhance efficacy of TRAIL receptor or poly I:C agonists that are currently under development.

*Development Stage:* Pre-clinical (in vivo validation).

*Inventor(s):* Thomas Sayers (NCI), Alan Brooks (NCI), Curtis Henrich (NCI), Poonam Tewary (NCI), James McMahon (NCI), Leslie Gunatilaka (University of Arizona), Ya-ming Xu (University of Arizona), and E.M. Kithsiri Wijeratne (University of Arizona).

*Intellectual Property:* US Provisional Application No. 62/292,974, entitled "Method of Sensitizing Cancer Cells to The Cytotoxic Effects of Apoptosis Inducing Ligands in Cancer Treatment," filed February 9, 2016.

**Publications**

1. Tewary P., Gunatilaka A.A. and Sayers T.J. (2016) Using natural products to promote caspase-8-