

issued in November 2009, encourages federal agencies to take deliberate and immediate action to eliminate fraud and improper payments. As part of the review of programs subsequent to this executive order, HHS has determined that additional information from each administering agency is necessary to assess grantee measures that are in place to prevent, detect or address waste, fraud and abuse in LIHEAP programs.

This Plan incorporates the data ACF must report to HHS regarding program integrity issues such as fraud prevention controls.

On January 27, 2014, ACF published a **Federal Register** Notice seeking 60 days of public comment on this proposed information collection. One state grantee provided comments. ACF revised the Plan to address the comments by ensuring that open field

boxes and attachment capability are available if the answer choices are insufficient to address the questions.

The revised model plan can be viewed on the OCS Web site at: <http://www.acf.hhs.gov/programs/ocs/programs/liheap>.

Respondents: State, tribal and territory governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Plan (First year—FY 2015)	210	1	2	420
Plan (future years)	210	1	0.50	105

Estimated Total Annual Burden Hours: First year—420; Future years—105.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office

of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Home Visiting: Approaches to Father Engagement and Father's Experiences.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S.

Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Home Visiting: Approaches to Father Engagement and Father's Experiences study. This study will document strategies used by selected home visiting programs to engage and serve fathers and the perceptions and experience of participating fathers. The findings will be of utility for many home visiting programs that desire to increase the active engagement of fathers to support the positive development of children as well as to organizations which provide oversight and technical assistance to home visiting programs. Through semi-structured discussions, respondents will be asked to comment on the most important strategies to support and facilitate fathers' participation.

Respondents: Administrators and key staff of selected home visiting programs, home visitors, and selected participating fathers and mothers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours (rounded)
Guide for Selecting Parents for Interviews	5	1	10	50	50
Interview Guide for Program Administrators	15	1	1.5	22.5	23
Interview Guide for Home Visitors	25	1	1.25	31.25	31
Interview Guide for Fathers—English and Spanish versions	40	1	1.27	50.8	51
Interview Guide for Mothers—English and Spanish versions	10	1	1.02	10.2	10
Home Visit Observation Sheet	10	1	0.17	1.7	2
Estimated Total Annual Burden Hours					167

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of

Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should

be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration, for Children and Families.

Karl Koerper,

OPRE Reports Clearance Officer.

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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.

Use of Antihistamine Compounds for the Treatment of Hepatitis C Virus

Description of Technology: The vast majority of people infected with Hepatitis C Virus (HCV) will have chronic infection. Over decades, this can lead to liver disease and liver cancer. In fact, HCV infection is the leading cause of liver transplants in the

U.S. Several new drugs have recently come into the market that will likely change the HCV treatment paradigm. However, the effectiveness of these new drugs can vary depending on the HCV genotype. Thus, there is still the need for additional new therapeutics against HCV.

The subject technology are small molecule compounds identified using a novel cell-based high throughput assay of HCV infection. The compounds are antihistamines that show potent antiviral properties against HCV. One advantage of these compounds is that they are already on the market for the treatment of allergic reactions and, thus, have been used extensively in humans and have excellent safety profiles with known pharmaceutical properties. The subject technology can also potentially be used in combination with other HCV therapeutics.

Potential Commercial Applications: Prevention or treatment of HCV infection.

Competitive Advantages: These compounds are already on the market and, thus, have known safety profiles and pharmaceutical properties.

Development Stage

- Early-stage
- In vitro data available

Inventors: Jake Tsanyang Liang (NIDDK), Juan Jose Marugan (NCATS), Noel Terrance Southhall (NCATS), Xin Hu (NCATS), Jingbo Xiao (NCATS), Shanshan He (NIDDK), Marc Ferrer (NCATS), Zongyi Hu (NIDDK), Wei Zhang (NCATS)

Intellectual Property: HHS Reference No. E-011-2014/0—US Provisional Patent Application No. 61/909,414 filed 27 Nov 2013

Licensing Contact: Kevin W. Chang, Ph.D.; 301-435-5018; changke@mail.nih.gov

Intranasal Nebulizer With Disposable Drug Cartridge for Improved Delivery of Vaccines and Therapeutics

Description of Technology: Intranasal delivery is a simple, inexpensive and needle-free route for administration of vaccines and therapeutics. This intranasal delivery technology, developed with Creare LLC, includes low-cost, disposable drug cartridges (DDCs) that mate with a durable hand-held device. The rechargeable-battery-powered device transmits ultrasonic energy to the DDC to aerosolize the drug and is capable of performing for eight hours at 120 vaccinations per hour. Potential applications for this platform technology include intranasal vaccination (e.g. seasonal or pandemic influenza vaccines) and intranasal

delivery of locally active (e.g. antihistamines, steroids) or systemically active (e.g. pain medications, sedatives) pharmaceuticals.

The DDCs themselves offer two unique benefits. First, all components that contact the active agent or the patient may be easily disposed of, which reduces the risk of patient cross-contamination and minimizes cleaning and maintenance requirements of the hand-held device. Second, DDCs provide a low-cost and simple method to package and distribute individual doses.

This technology also allows for significant dose-sparing. Preliminary studies have shown robust immune responses when this technology is used to delivery significantly reduced doses of Live Attenuated Influenza Vaccine in animal models. The intranasal nebulizer produces droplets sized for optimum deposition in the nasal airway. The small nebulizer droplets essentially “spray paint” the internal nasal airway, resulting in an increased tissue surface coverage that may enable a significant dose reduction. In contrast, currently available nasal delivery devices, such as nasal sprays and droppers, do not provide efficient intranasal delivery in humans because the large droplets they generate fail to coat a significant portion of the nasal airway. Large droplets also tend to drip out of the nose or down the throat, which can be unpleasant for the patient in addition to wasting a sizable portion of the active agent.

Potential Commercial Applications

- Intranasal delivery of vaccines and therapeutics
- Childhood vaccination programs, mass immunization campaigns, or response to epidemics

Competitive Advantages

- Safe, needle-less delivery
- No patient-to-patient contamination
- Long-life, rechargeable battery
- Consistent delivery and dose-sparing
- Nasal delivery of live-attenuated vaccines may be more effective than traditional injected vaccines
- Cost-effective
- Reduces biohazard waste
- May be administered by personnel with minimal medical training
- Easy means of delivery to children with fear of needles

Development Stage

- Prototype
 - In vitro data available
 - In vivo data available (animal)
- Inventors:** Mark J. Papania (CDC), et al.

Publication: Smith JH, et al. Nebulized live-attenuated influenza