for an average of 2,095 recall terminations annually, and we assume an average of 10 hours is needed for the corresponding information collection activity. To determine burden associated with recall status reports we divided the average number of annual submissions (36,127) by the average number of annual respondents (2,779) and assume 10 hours is necessary for the corresponding information collection, resulting in 361,270 hours annually.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications; § 7.49	2,779	445	1,236,655	0.05 (3 minutes)	61,832.75

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

To determine burden associated with recall communication disclosures described in § 7.49, we calculated an average of 445 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 61,832.75 burden hours annually.

These estimates reflect an overall decrease in the average number of annual responses by 245,846 and a decrease in the average number of annual burden hours by 70,949.25 since our last submission for OMB review and approval of the information collection.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07287 Filed 4–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Virtual Stakeholder Listening Session in Preparation for the 74th World Health Assembly

Subject: Office of Global Affairs: Virtual Stakeholder Listening Session in preparation for the 74th World Health Assembly.

Time and date: The session will be held on Thursday, May 13, 2021, from 10:00 a.m.–12:00 p.m. Eastern Time (ET).

Place: The session will be held virtually, and registration is required. Please RSVP by April 29, 2021 by sending your full name, email address, and organization to *OGA.RSVP@hhs.gov.* OGA encourages early registration.

Status: Open, but requiring RSVP to *OGA.RSVP@hhs.gov* to register.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 74th World Health Assembly—will hold an informal Stakeholder Listening Session on Thursday, May 13, 10:00 a.m.–12:00 p.m. ET. The listening session will be held virtually, and the meeting link will be shared with registered participants prior to the session.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation to the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 74th World Health Assembly. Your input will contribute to U.S. positions as we negotiate these important health topics with our international colleagues.

The listening session will be organized by agenda item, and participation is welcome from stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 74th World Health Assembly can be found at this website: *https://apps.who.int/gb/e/e_wha74.html.*

RSVP: Registration is required for the event. Please send your full name, email address, and organization to *OGA.RSVP@hhs.gov* to register. Please RSVP no later than Thursday, April 29, 2021.

Written comments are welcome and encouraged, even if you are planning on attending the virtual session. Please send written comments to the email address: *OGA.RSVP@hhs.gov.*

We look forward to hearing your comments related to the 74th World Health Assembly agenda items.

Dated: March 31, 2021.

Loyce Pace,

Director, Office of Global Affairs.

[FR Doc. 2021–07299 Filed 4–8–21; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request—60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 8, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Components Study of REAL Essential Curriculum.

Type of Collection: New.

OMB No. 0990–NEW—Office of Population Affairs—OASH–OS

Abstract

The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS) is requesting 3 years of approval by OMB on a new collection. The Components Study of REAL Essential Curriculum will identify the components that matter the most for promoting positive health behaviors and outcomes among adolescents. The study will examine program components (for example, content and dosage), implementation components (for example, attendance and engagement), and contextual components (for example, participant characteristics) to determine which components influence participant outcomes the most. In addition, the study will measure youth engagement in programming from various perspectives and examine the role of engagement as a mediating factor to achieving youth outcomes. Sites participating in the study will use the REAL Essentials Advance (REA) relationship curriculum, a popular program among federal pregnancy prevention grantees. The study will enroll schools from spring to fall 2022 (and possibly spring 2023, if necessary). The study will collect youth outcomes surveys at baseline, at program exit and 6 months following the completion of the program. The study will also collect extensive implementation data, which includes youth engagement exit ticket surveys after REA sessions, focus groups with youth and program facilitator logs and attendance records. Study staff will also interview facilitators and site leadership.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Youth Outcome Survey Baseline	Youth	507	1	40/60	338
Youth Outcome Survey—Program Exit.	Youth	507	1	40/60	338
Youth Outcome Survey—Six Month Follow-up.	Youth	480	1	40/60	320
Youth Focus Group Topic Guide	Youth	133	1	90/60	200
Youth Engagement Exit ticket	Youth	533	12	2/60	213
Fidelity Log	Program Facilitators	13	24	10/60	52
Facilitator Interview Topic Guide	Facilitators	5	2	1	10
District/CBO Leadership Interview Topic Guide.	District/School/CBO leadership	11	2	45/60	17
Total			44		1488

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–07285 Filed 4–8–21; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: N-butyldeoxynojirimycin To Treat Smith-Lemli Opitz Syndrome (SLOS) and Diseases That Exhibit a Similar NPC-Like Cellular Phenotype

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to SubRed Pty Ltd located in Australia, registered in Victoria.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Child Health and Human Development c/o National Cancer Institute's Technology Transfer Center on or before April 26, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs, Ph.D., Senior Technology Transfer Manager at Telephone (240)–276–5530 or at Email: *hubbsa@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

Intellectually Property

1. Great Britain Patent Application No. 712494.4, filed on June 27, 2007 [HHS Reference No. E–206–2007–0–GB–01];

2. PCT Patent Application No. PCT/GB2008/002207, filed June 26, 2008 [HHS Reference No. E–206–2007–0–PCT–02];

3. Issued Australian Patent No. 2008269585, filed on June 26, 2008, Issued July 2, 2015 [HHS Reference No. E–206–2007–0–AU–03];

4. Issued Canadian Patent No. 2691937, filed on June 26, 2008, Issued January 23, 2018 [HHS Reference No. E–206–2007–0–CA–04];

5. Issued European Patent No. 2182936, filed on June 26, 2008, Issued April 1, 2020 [HHS Reference No. E–206–2007–0–EP–05];

6. Issued US Patent No. 8,557,844, filed January 19, 2010, Issued October 15, 2013 [HHS Reference No. E–206–2007/0–US–06];

7. Issued United States Patent No. 9,428,541, filed on September 13, 2013, Issued August 30, 2016 [HHS Reference No. E–206–2007–0–US–09]

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: ''The use of N-butyldeoxynojirimycin in humans to treat Smith-Lemli Opitz Syndrome (SLOS) and diseases that exhibit a similar NPC-like cellular phenotype.''