

Information Collection on Cause-Specific Absenteeism in Schools and Evaluation of Influenza Transmission within Student Households

Request for OMB Approval of a Revision to a Currently Approved Information Collection

0920-1039

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Statement A

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Information Collection on Cause-Specific Absenteeism in Schools

Request for OMB Approval of a Revision to a Currently Approved Information Collection (OMB Control # 0920-1039)

Goal of the study: Evaluate the role of influenza-like illness (ILI)-specific school absenteeism in predicting community-wide influenza transmission and to detect within-household transmission of influenza in households from which a student has been absent from school due to ILI.

Intended use of the resulting data: To strengthen the evidence-base for CDC's Pre-Pandemic Guidance on the school-related mitigation measures during an influenza pandemic.

Methods to be used to collect: Phone interviews, in-person interviews, and Biospecimen collections

The subpopulation to be studied: Students in the Oregon School District in Wisconsin and their household members.

How data will be analyzed: A time series analysis will be done comparing ILI absenteeism and influenza rates in school children with community influenza to find a correlation between ILI absenteeism and community influenza rates.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for approval of a revision to the currently approved information collection, "Information Collection on Cause-Specific Absenteeism in Schools and Evaluation of Influenza Transmission within Student Households" (OMB Control No. 0920-1039). The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests three years of approval.

This information collection will be conducted by the University of Wisconsin-Madison research team with technical assistance in study design, data analysis, and preparation of manuscripts resulting from this study from the CDC staff. The project will be conducted in pre-kindergarten to 12th grade (4K-12) schools of the Oregon school district, Wisconsin, over the four school years: 2017--2021. CDC will submit a revision/extension ICR in 2020 to get OMB approval for the final year of the study.

Since obtaining OMB approval in December 2014, 651 students absent from school due to Influenza-like illness (ILI) were enrolled in the study. Of them, 58% were positive for at least one respiratory pathogen included in the PCR panel that tests for presence of 17 common respiratory viruses, and 27% of the students were found to be positive for influenza. It was demonstrated that absenteeism due to ILI in school children was highly correlated with PCR-confirmed influenza in enrolled school children ($r=0.73$; $P<0.001$) and with medically-attended influenza in the surrounding community ($r=0.72$; $P<0.001$) suggesting that ILI-specific school absenteeism can be considered a useful tool for predicting influenza outbreaks in the surrounding community. However, more observations during influenza seasons caused by other influenza strains are needed to make these findings more robust.

This information collection aims to improve our understanding of the role of influenza-like illness (ILI)-specific absenteeism in schools in predicting community-wide influenza transmission and to detect within-household transmission of influenza in households from which a student has been absent from school due to ILI. Insights gained from this information collection will be used to strengthen the evidence-base of CDC's Pre-Pandemic Guidance prior to the next pandemic.

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A1) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from one state or possession into any other state or possession. These regulations are codified in 42 Code of Federal Regulations (CFR) Part 70 (Attachment A2). CDC is authorized to collect these data under the Public Health Service Act (42 USC 241), Section 301 (Attachment A3). The information collection for which approval is sought is in accordance with DGMQ's mission to prevent the introduction, transmission, or spread of communicable diseases within the United States.

Due to children's naïve immunity, their susceptibility to infectious diseases, and congregation of children at schools, schools serve as amplification points for influenza transmission (1). Therefore, the collection of ILI-specific absenteeism could provide information needed to detect influenza outbreaks early, before infection spreads to a wider community. Such early detection of outbreaks will enable public health and school authorities to timely implement appropriate infection control and prevention measures.

School children are frequently the main introducers of influenza to their families (2-4). Evaluating influenza transmission within households where students are absent from school because of ILI may serve as an additional layer of influenza surveillance, and could contribute to understanding of influenza transmission dynamics within the surrounding community. This revision to the currently approved information collection adds a household transmission component, in which information and biospecimens will be collected from household members of students absent from school because of ILI. In the currently approved information collection, information and biospecimens are collected only from students who were absent from school because of ILI. This revision aims to enhance current knowledge and understanding around the introduction of influenza infection to households that have school-age children, as well as within-household influenza transmission.

Experiences from 2009 H1N1 influenza pandemic when persons 18 years of age and younger were the most susceptible group further highlight the need for additional research on ILI-related absenteeism and may prompt school-related mitigation measures, which may be the only means to slow down the spread of emerging respiratory infections for which vaccines and pharmaceutical prophylaxis are not yet available.

This information collection will focus on ILI but may also be applicable to outbreaks caused by other serious acute respiratory infections, with similar modes of transmission as influenza.

2. Purpose and Use of the Information Collection

The purpose of this revised information collection is to evaluate the role of ILI-specific absenteeism in schools in predicting community-wide influenza transmission and to detect within-household transmission of influenza in households from which a 4K-12 grade student was absent from school due

to ILI. Insights gained from this information collection will strengthen the evidence-base for CDC's Pre-Pandemic Guidance on the school-related mitigation measures during an influenza pandemic.

When a pandemic first emerges, CDC will assess the situation and develop mitigation guidance for state and local authorities, aiming to provide the best technical advice, based on the best available data on clinical severity and viral transmissibility. Implementation will depend on local conditions, including (but not limited to) patterns of local disease spread (e.g., outbreaks in schools) and hospital and medical resources. School-related measures implemented early and in a coordinated and targeted approach are likely to have the greatest impact on slowing influenza transmission during a pandemic.

Although the findings will not be generalizable beyond the settings or populations from which the information is collected, state and local authorities will be able to use the mitigation guidance (and the updated evidence-base following this information collection) to facilitate decision-making and to inform their communities and mobilize them to take action.

This revision to the currently approved information collection adds information and biospecimen collection from household members of students absent from school because of ILI. In the currently approved project, information and biospecimens are only collected from students.

This information collection will be implemented in collaboration with the University of Wisconsin and will target students attending pre-kindergarten to 12th grade (4K-12) schools. The University of Wisconsin will implement the project in Oregon School District, Wisconsin at the following six schools: Oregon High School, Oregon Middle School, Rome Corners Intermediate, Netherwood Knoll Elementary, Prairie View Elementary, and Brooklyn Elementary. Student information will be collected on the number, duration, and specific cause of school absences and obtained through telephone and in-person interviews. Household member information will be collected on household composition; influenza vaccine status; symptoms and severity of illness; related healthcare visits, diagnosis, and treatment; and on missed work or school.

Students and parents/guardians in the school district will be informed about the opportunity to participate in the study at school events, through promotional materials (flyers, postcards, posters, newspaper advertisements – attachments D1-D4) distributed around the community, and also using an existing call-in absentee messaging system. In the absentee phone line, the existing message will be modified to include an invitation to participate in the study.

When a student is absent from school and has symptoms such as a sore throat, fever, or other respiratory symptoms, his/her parent or guardian, or an adult student (age 18 or older) him/herself, can call the study telephone number directly to learn more about participation in this study. The phone will connect to an enrolling surveillance assistant. The enrolling surveillance assistant will describe the program and will screen for inclusion and exclusion criteria using the Screening form (Attachment C2 – Screening form). If the student meets eligibility criteria and is willing to proceed, arrangements will be made for a face-to-face household visit for obtaining informed consent and assent for the student (Attachment C3 – Consent/Assent Form. On average, three students will be enrolled per day during influenza season (between week 40 and week 20). During the household visit, trained surveillance assistant will use the Acute Respiratory Infection and Influenza Surveillance Form (Attachment C4 - Acute Respiratory Infection and Influenza Surveillance Form) to collect information about the student's illness. Biospecimens will also be obtained by a surveillance assistant during the household visit via nasopharyngeal or oropharyngeal swab.

In this revised information collection, household members will also be offered to participate in the information collection, whereby informed consent and assent for the household members will be obtained (Attachment C3a – Household Member Consent/Assent Forms). The surveillance assistant will collect and record data on consenting household members using the Household Study Form (Attachment C4a –Household Study Form). Household members not present at the time of the household visit, will have the option to complete the study form once they return home and consent/assent to participation, if it is within 24 hours of the initial visit. A designated adult will assist in completion of the form for participating children. Additionally, during the home visit, the research team will obtain nasopharyngeal or oropharyngeal swabs for RT-PCR from consenting household members present at the time of household visit. Participating household members not present at the time of the home visit will provide a nasal swab specimen within 24 hours of the home visit to be stored in the refrigerator until it can be collected by the study team. Seven days following the home visit, all household participants and the designated adult for participating children, excluding the student participant, will complete the “Follow-up” portion of the form (Attachment C4a- Household Study Form) and the designated adult will obtain nasal swab specimens from all household members except for the student participant, to be stored in the refrigerator until specimen pick-up by the research team.

Attachments C2-Screening form, C3-Consent/Assent Form and C4-Acute Respiratory Infection and Influenza Surveillance Form were approved as parts of the current information collection. Attachments C1-School District Approval Letter, C3a-Household Member Consent/Assent Forms, C4a-Household Study Form, C5-University of Wisconsin - IRB approval and C6-CDC IRB deferral notice are either updated (C1, C5 and C6) or newly added (C3a and C4a) as part of this revision.

Appropriate statistical models will be used to assess the utility of these data to predict community-wide influenza transmission according to established local, state, and national influenza surveillance systems.

This information collection will target children with some screening information gathered from parents/guardians of students, gather consent from parents/guardians and other adult household members, as well as age-appropriate verbal assent gathered from students and other children in participating households, followed by surveillance information. Additionally, aggregate data on ILI-specific absenteeism will be gathered from the school district and data on immunization will be shared by the Wisconsin Immunization Registry.

Information in the currently approved information collection that will be gathered from students who were absent from school due to ILI (for students younger than 18 collected from parents/guardians) (Attachments C2-Screening Form and C4 Acute Respiratory Infection and Influenza Surveillance Form) includes the following:

- Demographic information
- Reports of exposure to other persons with ILI symptoms within 1-3 days
- Information on recent travel
- Information on symptoms (measured temperature, presence of symptoms compatible with ILI) and treatment
- Information on visits to healthcare provider
- Information on antiviral medication

Information that will be collected by the Oregon school district using existing absentee monitoring system from each participating school and will be used by the research team:

- Number of students absent due to all causes, by grade for each day of the school year.
- Number of students absent due to ILI by grade for each day of the school year

Information that will be gathered from Wisconsin Immunization Registry:

- Vaccine history of participating students. This will be done by an approved study research assistant using the look-up function.

This revision includes information that will be gathered from children and adult household members on Day 0 (day of home visit) and Day 7 following the home visit (Attachment C4a- Household Study Form), as follows:

- Household composition
- Information on influenza vaccine status
- Information on symptoms and severity of illness
- Information on related healthcare visit
- Information on missed work or school

In order to obtain information on respiratory pathogens circulating at times when absences are low, University of Wisconsin will also seek to collect reports of illnesses among students who remain in school.

3. Use of Improved Information Technology and Burden Reduction

Information collection will be obtained through telephone contact and in-person interviews and does not involve the use of information technology. Information collection tools for the proposed project are included in the attachments and have been reviewed and approved by the University of Wisconsin as well as by DGMQ. The number of questions posed has been held to the minimum required in order to elicit the necessary information. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

4. Efforts to Identify Duplication and Use of Similar Information

Using school absenteeism data to predict influenza outbreaks has been suggested in previously done studies (5-7). Although several studies (8-10) have demonstrated usefulness of absentee data for detection of infection disease outbreaks, these studies were conducted in developing countries where school systems are unique for the respective country, and, therefore, the findings are not fully applicable to the United States. It was also demonstrated that non-disease specific absenteeism data alone are of little use for school-based influenza surveillance (11). On the other hand, influenza-specific absenteeism data from schools were better able to predict a community outbreak of influenza than all-cause absenteeism. There is an evident lack of data both on ILI-specific absenteeism as a predictor of the community-wide influenza outbreaks and on within-household transmission of influenza where a student has been absent due to ILI. As such, it is not expected that any of the information collected under this package is duplicative or is already in the possession of the federal government or other organizations that study or promote school-related mitigation measures. The proposed project will allow DGMQ to obtain important information from school settings in order to strengthen the evidence base for

CDC's Pre-Pandemic Guidance. DGMQ will make all reasonable effort to ensure that the information collection does not overlap with other projects on infectious disease control measures in school settings.

5. Impact on Small Businesses or Other Small Entities

Small entities, including small governments (i.e. county and local public health and school officials), will be included in the proposed information collection. A small government is defined as a government jurisdiction of a city, county, town, township, school district, or special district with a population of less than 50,000. Questions will be held to the absolute minimum required for the intended use when participants could include officials representing small government offices (e.g., obtaining aggregate information on student absences for defined period of time).

6. Consequences of Collecting the Information Less Frequently

CDC is requesting that respondents record and report any instance of absence from school. The proposed revised information collection is required to strengthen the evidence-base for mitigation measures in school settings. The lack of additional information on ILI-specific absenteeism and associated within-household transmission will negatively impact the federal government's capacity to provide data driven guidance during the next pandemic. There are no legal obstacles to reducing burden. Burden to individuals has been minimized and only necessary fields are included in the collection instruments.

Due to the congregation of children at schools and their susceptibility to many infectious diseases, school-based infectious disease outbreaks frequently precede disease transmission in the wider community. Therefore, the collection of cause-specific absenteeism could provide important information needed to protect school-aged children from influenza and the impact of outbreaks on the wider community. Timing of influenza season is usually shorter than the academic year (on average, it lasts from October-end of March, peaking in January), and intensity of influenza activity varies across the season and between different influenza seasons. Therefore, it is important to collect information for the study consistently during the academic year in order to maintain the validity of the study results. Findings from this information collection will be used to validate existing pandemic mitigation strategies, refine current strategies if needed, and strengthen the evidence-base for decision making on implementation of school-related measures during a pandemic.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

One information collection activity in Madison, Wisconsin will be conducted under the auspices of this request. Individual respondents, including household members, may be asked to respond to investigators more than once following subsequent ILI-related absence of the same student if at least 7 days have passed since his/her previous ILI-related absence. All materials related to this information collection are included in this package as specified in regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

8a. A 60-day Federal Register notice was published in the Federal Register on April 27, 2017, Vol. 82, No. 80, pages 19373-19374 (Attachment B). Two non-substantive public comments were received (B1 and B2). Because there was no return address, no responses were sent.

8b. Consultation

The following agencies and organizations outside of CDC have been consulted on the need for data collection with the audiences, and for the purposes, described in this information collection:

- In consultation with University of Wisconsin-Madison on the need for and process of data collection with the audiences described in this package:

Jonathan Temte, MD, PhD, Principal Investigator
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E-mail: Jon.Temte@fammed.wisc.edu

- In consultation with University of Michigan the need for additional school-related mitigation measure research was identified in 2013.

Allison Aeillo, PhD, Epidemiologist
Phone: 734-615-9213
E-mail: aielloa@umich.edu

- In consultation with University of Utah the need for appropriate statistical methods for mitigation measure research was identified in 2013.

Molly Leecaster, PhD, Statistician
Phone: 801-585-6924
E-mail: Molly.Leecaster@utah.edu

- In consultation with University of Pittsburgh the need for additional school-related research was identified in 2013.

Charles Vukotich, MS, Senior Program Manager
Phone: 412-383-2882
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9. Explanation of Any Payment or Gift to Respondents

DGMQ will not directly offer cash incentives to the participants targeted in this information collection. However, the University of Wisconsin organizations will provide small, tangible tokens of appreciation for participants' time.

All students who were absent from school due to influenza-like illness ("a-ILI student") (or parents of younger students) participating in the information collection on cause-specific student absenteeism will receive a \$20 gift card. Each "a-ILI student's" household participating in the household transmission arm of the study will be provided with a \$50 gift card after the home visit is completed.

The IRB at the University of Wisconsin, DGMQ's implementing partner, does not view this amount as coercive, but appropriate to the time involved and the biospecimens obtained.

The information collection on cause-specific student absenteeism has been ongoing since January 5, 2015, and from the very beginning to date participating students have been receiving the same token of appreciation (a \$20 gift card).

The household transmission substudy was initiated by The University of Wisconsin in 2016 outside the scope of this ICR. CDC did not participate in the household substudy from 2016 until now. Now, however, the household substudy is being included in this ICR to correspond with the renewed cooperative agreement between CDC and the University. When the University of Wisconsin initiated the household substudy in 2016, it utilized a \$50 token of appreciation for participation. The average household includes three additional participants so the \$50 token of appreciation was seen as comparable to the ORCHARDS student study and within the scope of OMB's standards (~\$17 per person for multiple information and biospecimen collections). In addition, participating households are required to coordinate with the research staff to permit form and biospecimen pick-up in a timely manner (usually on Day 7).

On average, participation in the household transmission component includes seven data collection forms and seven biospecimen samples for lab testing (initial and follow-up form for the household members, plus a follow-up sample and follow-up form for the student-child who was the "index case" that links that household with the school in which the main study is implemented).

Since 2016, the University of Wisconsin has experienced a steadily increasing rate of participation in the household transmission substudy, which rose rapidly from 38% of eligible households in the initial school semester of the household transmission substudy implementation (fall semester 2016/17) to the current participation rate of more than 70%. As ORCHARDS study participation has relied heavily on "word of mouth" recommendation from past participants, a reduction of previously established incentives at this time could reduce future participation in the study.

Based on Wisconsin's early success with the household component, CDC and Wisconsin have an opportunity now to consolidate the two studies within this ICR and increase CDC's level of engagement overall. As part of this consolidation, CDC is requesting that Wisconsin be allowed to maintain the same incentive structure to limit any interruption or negative effects on participation.

Because the \$20 token of appreciation for students is only for participation in the cause-specific student absenteeism component of the study, there is no overlap in the calculations for the tokens of appreciation offered to the student-child "index case" and the household participants in the household transmission component of the study. The \$20 token of appreciation will be given to student participants regardless of whether or not their households participate in the household substudy.

Incorporating modest tokens of appreciation to aid in recruitment for information collection is standard practice among commercial market researchers. For a number of reasons, this practice is also appropriate for the information collection covered by this package.

The most important aspect of an incentive plan may be its potential for reducing response bias, underreporting bias, and similar sources of error. Findings from the National Survey of Family Growth (a study in which childbearing and family planning patterns are collected from young women) demonstrated that incentives not only had positive effects on response rates, but they also increased the accuracy of reporting (12). This population will be included in our study population as part of our proposed school absentee monitoring system projects. Tokens of appreciations are often necessary for

testing in order to ensure that those who are willing to participate are as representative as possible of the wider public. Failure to provide a basic incentive may bias samples in the direction of well-educated individuals who are unlikely to be representative of the entire target population.

In the National Adult Literacy Survey by Berlin and colleagues (13), a \$20 incentive resulted not only in higher response rates from the sample cohort, but also in lower costs per completed case-report than the comparison group. Importantly, the incentives provided higher response rates from adults with lower-than-average levels of education and basic literacy and numeracy skills.

Empirical evidence suggests that motivation is increased when an incentive is present for research. Without providing minimal levels of monetary compensation, insufficient numbers of participants will likely participate and results will not be useful (13). In addition, there is substantial evidence that monetary incentives increase response rates to surveys. In a meta-analysis of 38 experiments and quasi-experiments, researchers found that nonmonetary gifts were significantly less effective than cash in generating survey responses, and noted that offering pre-paid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups (14).

DGMQ will not directly provide remuneration to project participants. However, during the recruitment process, the University of Wisconsin organizations will provide small tokens of appreciation to participants (see above). To account for differences in local culture and socioeconomic factors, project investigators have worked with contractors and the University of Wisconsin to ensure that incentive type and value are appropriate and do not have the effect of coercing individuals to participate.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The revised information collection described in this package has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). The privacy act is applicable. Individuals will be responding to the information collection completely voluntarily and will be covered by Privacy Act System Notice 09-20-0160, Records of Subjects in Health Promotion and Education Studies. Persons covered by the system notice include adults and children, including health and education agency administrators, school health personnel, teachers, parents, and students who participate in studies and surveys designed to obtain data on their knowledge, attitudes, and reported behavior related to a variety of health problems and/or other potentially preventable conditions of public health significance; also included are control group participants.

DGMQ, contractors, and the University of Wisconsin organizations will follow procedures for securing and maintaining privacy during all stages of information collection. Participants will be recruited directly from project schools and all students who are recruited will have parental consent using Attachment C3 Consent/Assent form for student and Attachment C3a Consent/Assent form for household members. The University of Wisconsin and contractors will collect and analyze the project specific data. DGMQ will provide technical assistance in the design, implementation, and analysis of the project but will not be contact with project participants (and will only have access to coded data). All information provided by participants will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Participants will be informed prior to participation that their responses will be treated in a secure manner.

Participants will be advised of the nature of the information collection activity, the length of time it will require, and that participation is purely voluntary. Participants will be assured that no penalties will

occur if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human subjects.

The proposed information collection has been reviewed and approved by the IRB at the University of Wisconsin (with CDC deferral to that academic institution's IRB). Prospective participants will receive information on the purpose and sponsorship of the project, their rights as participants, risks and benefits in participating, and contacts for more information about the project. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project.

For the project implemented by the University of Wisconsin, project staff will request verbal consent during initial telephone contact with the student's parent/guardian when assessing eligibility. During the in-person home visit, parental/guardian written consent will be obtained for students and household members < 18 years of age. Verbal assent will be obtained from students and household members aged 4 to 6 years of age, written assent will be obtained from children aged 7 to 14 years, and written consent will be obtained from students 15 years or older. Adult household members will provide written consent.

All data will be stored in secured electronic files with the University of Wisconsin and will be accessible only to staff directly involved in the project. All members of the project will be required to sign a statement pledging their personal commitment to guard the security of data. Online information collections will conform completely to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987]; all information will be maintained in a password protected secure location. All project personnel having access to individual identifiers will sign non-disclosure agreements. DGMQ will have access to only coded data (all links to individual identifiers will be maintained by the University of Wisconsin organizations).

No system of records is being created for this information collection. However, information collected as part of this package from students and parents will be covered by Privacy Act System Notice 09-20-0160 Records of Subjects in Health Promotion and Education Studies, Federal Register /Vol. 51, No. 226 /Monday, November 24, 1986/ PP 42484-42485.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

The protocols and tools included in this information collection request have been reviewed and approved by the IRB at the University of Wisconsin with CDC review and deferral to the University. Approval letters from each academic institution and CDC's deferral approval are included in the attachments (Attachments C5 University of Wisconsin - IRB approval and Attachment C6 - CDC IRB deferral notice).

Justification for Sensitive Questions

Mitigation measure research typically does not involve questions of a sensitive nature. However, questions about the reasons for absences could be considered sensitive by some participants. A portion of participants could also consider questions about race, ethnicity, or other demographic characteristics to be sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some participants may feel uncomfortable answering particular questions about their individual experiences, level of disease awareness, and/or adopted preventative behaviors (or lack

thereof) associated with various diseases (e.g. influenza vaccination). Such questions, when asked, are necessary for the purposes of this information collection. To minimize psychological distress, the moderator or information collection instructions will inform participants that they do not have to respond to any questions they do not want to answer and that they may stop participating at any time. In addition, a subject matter expert from the University of Wisconsin will be available to answer questions from participants following the information collection activity.

12. Estimates of Annualized Burden Hours and Costs

This information collection will be implemented in collaboration with the University of Wisconsin and will target students attending 4K-12 schools and their household members in Madison, Wisconsin. Information will be collected on student absences for enhanced cause-specific school absentee monitoring and within-household influenza transmission, as previously described.

We outline the estimated burden hours for the proposed project in Table 12A. The burden table provides estimated annualized burden hours and costs across the different project locations.

For each year of the study, we will initially target 345 students who will be interviewed for presence of ILI symptoms using the Screening Form. We estimate that 87% of students will meet eligibility criteria resulting in enrollment of 300 students. For these 300 eligible students, the Acute Respiratory Infection and Influenza Surveillance Form will be filled out and biospecimen (nasal or oropharyngeal swab) will be collected by the study team. The biospecimen collection does not include any standardized information collection, but a form has been provided as a stand-in (Student biospecimen form). This is estimated to take no longer than five minutes. A student can be included in the study again, following his/her subsequent absence if 7 days have passed since his/her last enrollment.

University of Wisconsin staff estimates that it will take less than 5 minutes to respond to the initial screening call (Screening Form), less than 15 minutes to complete the in-person interview (Acute Respiratory Infection and Influenza Surveillance Form), and less than 5 minutes to complete the biospecimen collection.

A participation rate of 80% from student households is expected, yielding 240 participating families from 300 enrolled students. We estimate that the average household has 4 members including the participant. Accordingly, we estimate 720 participating household members (which does not include the student). We estimate that it will take less than 5 minutes for household members to complete the in-person survey twice: on Day 0 and Day 7 (Household Study Form). Biospecimen collection will likewise take less than 5 minutes per day for household members to complete on both Day 0 and Day 7 for a total burden of 10 minutes per interaction. Also on Day 7, students' parents will complete the household study form on behalf of each participating student (five minutes). The total burden to participants is estimated at 419 hours annually.

In this revision, the number of participating students decreased from 500 in the originally approved information collection to 300. Also, the number of responses per respondent decreased from 4 to 1. Therefore, there is a substantial reduction in burden hours from 834 in the approved information collection to 419 in this revision.

Table 12-A: Estimated Annualized Burden to Participants for example projects

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Student Component					
Parents of children/adolescents or adult students (≥18 yo) attending schools	Screening Form	345	1	5/60	29
	Acute Respiratory Infection and Influenza Surveillance Form	300	1	15/60	75
	Household Study Form A	300	1	5/60	25
Student	Biospecimen collection (Day 0)	300	1	5/60	25
Household Component (80% Participation Rate)					
Parents of children/adolescents or adult students (≥18 yo) attending schools	Household Study Form B (Day 7)	240	1	5/60	20
Student	Biospecimen collection (Day 7)	240	1	5/60	20
Household members	Household Study Form B (Day 0 and 7)	720	2	5/60	120
Household members	Biospecimen collection (Day 0 and 7)	720	2	5/60	120
TOTAL					434

Table A.12-B presents the calculations for cost of respondents' time using the general public's mean hourly wages. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website, specifically originating from the 2016 National Occupational Employment and Wage Estimates for the United States (http://www.bls.gov/oes/current/oes_nat.htm). An average hourly salary of approximately \$23.86 is assumed for all participants, based on the Department of Labor (DOL) National Compensation Survey. The average salary was used rather than attempting to estimate salaries for different audiences due to the scope of this package. With an annual burden of hours of 419 the overall cost of participants' time for the example information collections is estimated to be a maximum of \$8,804.34.

The total respondent costs are summarized below in Table A.12-B.

Table A.12-B: Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden House	Hourly Wage Rate	Total cost burden
Parents of children/adolescents or adult students (≥18 yo) attending schools	Screening Form	29	\$23.86	\$691.94
	Acute Respiratory Infection and Influenza Surveillance Form	75	\$23.86	\$1,789.50
	Household Study Form A/B	45	\$23.86	\$1,073.70
Student	Biospecimen collection	45	\$0.00	\$0.00
Household members	Household Study Form B	120	\$23.86	\$2,863.20
Household members	Biospecimen Collection	120	\$23.86	\$2,863.20
TOTAL				\$9,281.54

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no cost or burden to respondents other than their time.

14. Annualized Cost to the Government

There is no equipment or overhead cost. The only cost to the federal government would be the salary of CDC staff supporting the information collection activities and associated tasks.

Table A.14-A: Estimated Annualized Cost to the Government per Activity and Total

Estimated Annualized Cost to the Government per Activity and Total	
Cost Category	Estimated Annualized Cost
Federal employee costs, per information collection (15% FTE of two GS-14 step 6 at ~\$120,000/year)	\$8,479
Contractual costs for an information collection (e.g. facility rental, moderator/interviewer, participant recruitment, translations, transcriptions and final reports) --School absentee project = \$600,000/year	\$600,000
Cost per information collection	\$608,479

Total cost for annualized information collections	\$608,479
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15. Explanation for Program Changes or Adjustments

Since getting OMB approval in December 2014, 651 students absent from school due to ILI were enrolled in the study. Of them, 58% were positive for at least one respiratory pathogen included in the PCR panel that tests for presence of 17 common respiratory viruses, and 27% of the students were found to be positive for influenza. It was demonstrated that absenteeism due to ILI in school children was highly correlated with PCR-confirmed influenza in enrolled school children ($r=0.73$; $P<0.001$) and with medically-attended influenza in the surrounding community ($r=0.72$; $P<0.001$) suggesting that ILI-specific school absenteeism can be considered a useful tool for predicting influenza outbreaks in the surrounding community. However, more observations during influenza seasons caused by other influenza strains are needed to make these findings more robust.

This revision adds household transmission component to the ongoing approved information collection, In addition to collecting data and biospecimens from students who were absent from school because of the ILI, information and biospecimens will also be collected from household members of these students. This revision aims to enhance current knowledge and understanding of introduction of influenza infection to households that have school-age children as well as within-household transmission.

16. Plans for Tabulation and Publication and Project Time Schedule

In collaboration with the University of Wisconsin, DGMQ started initial data collection in September 2014. Revised data collection is anticipated to start after receiving OMB in 2017. DGMQ expects to begin tabulating data at the end of the school year (in June 2018) and publish the results from this information collection upon completion of the project after June 2021. Results will be presented at professional conferences and in peer-reviewed journals. We do not aim to generalize results obtained from the project covered by this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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ATTACHMENTS

- A1. Section 361 of the Public Health Service Act (42 USC 264).
- A2. 42 Code of Federal Regulations Part 70 Interstate Quarantine
- A3. Section 301 of the Public Health Service Act (42 USC 241)
- B. 60-Day Federal Register Notice
- B1. Public comment
- B2. Public comment
- C1. School District Approval Letter
- C2. Screening form
- C3. Consent/Assent Form
- C3a. Household Member Consent/Assent Forms
- C4. Acute Respiratory Infection and Influenza Surveillance Form
- C4a. Household Study Form
- C5. University of Wisconsin - IRB approval
- C6. CDC IRB deferral notice
- C7. Biospecimen collection
- D1. Student participant packet
- D2. Recruitment flyer 1
- D3. Recruitment flyer 2
- D4. Newspaper advertisement