Information Collection on Cause-Specific Absenteeism in Schools (Pittsburgh Location)

Request for OMB Approval of a New Information Collection
(OMB Control # 0920-XXXX)
Expiration date: XX-XX-XXXX

March 20, 2015

Statement A

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Table of Contents

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This is a request for a new information collection. CDC is requesting a 3-year approval to collect information.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 approval of a new information collection on Cause-Specific Absenteeism in Schools. The project is implemented under the cooperative agreement between Johns Hopkins University and CDC. This information will be collected for a period of three years in students from schools of three school districts in Allegheny County, Pennsylvania: Fox Chapel School District, Propel Charter School District and Canon-MacMillan School District. Data collection will be conducted by the research team at the University of Pittsburgh with technical assistance provided by CDC in project design, data analysis, and preparation of manuscripts resulting from this project.

This information collection aims to improve our understanding of the role of cause-specific absenteeism in schools in predicting community-wide influenza transmission. We will obtain information on how influenza spreads among children in school and between children and the community. This will lead to greater accuracy in determining where, when, and for how long to implement school-related influenza mitigation measures. Insights gained from this information collection will be used to strengthen the evidence-base of CDC's Pre-Pandemic Guidance prior to 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.

Influenza pandemics are inherently unpredictable, caused by newly emerged viruses that differ in geographical and biological origin, transmissibility, drug sensitivity, and capacity for causing severe illness (1). When a pandemic first emerges, the most effective countermeasure— a vaccine against the new pandemic virus—may not be available for 4 to 6 months, and may not be produced in sufficient quantities to immunize all risk groups (including school-aged children) for 6 to 8 months (2). Moreover, antiviral medications, which can ameliorate symptoms if provided within 24-48 hours of onset, may not

be effective against a new pandemic strain or may quickly become ineffective due to the emergence of drug resistance.

A comprehensive community strategy for mitigating the effects of a pandemic must, therefore, address not only medical countermeasures (3-6) but also school related mitigation measures — one of our first lines of defense at the earliest stages of a pandemic. To be effective, these measures must be strategically targeted and tailored to the pandemic severity. Because most school-related measures do not require medical resources or specialized equipment, they are available to public health officials in all state and local communities.

The 2007 *Community Strategy for Pandemic Influenza Mitigation in the US* was developed with a severe pandemic in mind, amid fears that the virulent avian influenza A (H5N1) virus—which re-emerged in Southeast Asia in 2003 and spread to Africa, the Middle East, and Europe—might evolve into a highly dangerous human pandemic strain (7). A new H5N1 virus was thought most likely to emerge overseas, providing some lead-time to prepare for a U.S. response that might make use of a stockpiled pre-pandemic H5N1 vaccine. Instead, the next pandemic virus turned out to be a human H1N1 strain (a quadruple reassortant with genes from influenza viruses of humans, birds, European swine, and Asian swine) that apparently emerged in Mexico and was first identified as a new strain in the United States on April 19, 2009, when cases were reported in two children in adjacent California counties. On April 23, CDC confirmed that the influenza cases in Mexico and California were caused by the same H1N1 strain.

Implementation of school-related measures was especially important during the earliest stage of the H1N1 pandemic, because a pandemic vaccine was not available until October (6 months later), and sufficient stocks to immunize all school-age children were not available until December. However, retrospective review of the U.S. government response to the pandemic identified limited information on the effectiveness, acceptability, and feasibility of school measures, especially for prolonged school closures, to slow the spread of the pandemic virus. Guidance updates will require an evidence-based rationale for the use of school-related measures.

Due to the congregation of children at schools and their susceptibility to many infectious diseases, children are frequently the main introducers of influenza to their families (8-10), and schools serve as amplification points for influenza transmission (11). Therefore, the collection of ILI-specific absenteeism could provide information needed to detect influenza outbreaks in schools and protect school-aged children from infectious diseases, which subsequently may enable a reduction in the impact of outbreaks on the wider community. This information could in turn inform the timely implementation of appropriate school-related control and prevention measures.

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 that may prompt school-related mitigation measures. Such measures 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 Information Collection

The purpose of this new information collection is to better evaluate the role of cause-specific

absenteeism in schools in predicting community-wide influenza transmission. 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, including the possibility of schools closures, implemented early and in a coordinated and targeted approach are likely to have the greatest impact on slowing influenza transmission during a pandemic. However, limited information is available about where, when, and for how long to implement these school-related measures. The project described in this information collection request aims to address this knowledge gap.

Though the findings will not be generalizable beyond the settings or populations from which the information is collected, state and local authorities will be able 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.

3. Use of Improved Information Technology and Burden Reduction

To the extent possible, partner organizations will employ electronic technology (web-based surveys) to collect information to reduce respondent burden and to aid in information processing and reporting efficiency. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Information collection will be obtained through telephone contact and in-person interviews, and through web-based surveys. Efforts will be made to encourage respondents to reply through telephone contact and by completing the web-based surveys when possible in order to reduce the potential respondent burden. Information collection tools (e.g., eligibility screen questions and screenshots of web-based surveys) for the proposed project are included in the attachments and have been reviewed and approved by each academic institution, respectively, as well as by DGMQ. The number of questions posed has been held to the minimum required in order to elicit the necessary information.

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 (12-14). Although several studies (15-17) have demonstrated usefulness of absentee data for detection of infection disease outbreaks, these studies were conducted in developing countries and 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 (18). 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 on ILI-specific absenteeism as a predictor of the community-wide influenza outbreaks. 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 information collection is required for DGMQ to strengthen the evidence-base for mitigation measures in school settings. The lack of additional information on cause specific absenteeism 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 ILI-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. Therefore, it is important to collect information for the project consistently during the academic year in order to maintain the validity of the project 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 project in Pittsburgh, Pennsylvania will be conducted under the auspices of this request. Individual respondents (parents and children) may be asked to respond to investigators more than once; however, this is only the case if more than one absence is taken from school. A record of multiple absences is necessary to understand the causes of students not being in school. Information will also be collected from some families on symptoms related to possible acute respiratory infections on a weekly basis for a total of 12 weeks. This will allow DGMQ and partner organizations to capture illness data that may not be related to a school absence (i.e. students with a mild case of influenza may still choose to attend class). 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 Tuesday, September 16, 2014, Volume 79, No. 179, p. 55495. (Attachment B). One non-substantive comment was received and CDC's standard response was 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 Michigan the need for additional school-related mitigation measure research was identified in 2013.

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

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

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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, partner organizations will provide small, tangible tokens of appreciation for participants' time. In Pittsburgh, Pennsylvania, the following incentives will be offered:

- Each school will receive an Apple IPad (current model) to raffle among participating students
- Each school district will receive an Apple IPad (current model) to raffle among students who have been tested for influenza (provided swab)
- Additional small awards (e.g., flash drives, pens, pizza parties) may be made to available to school for students who participate (the value of the items will be < $10.00). These incentives will be distributed through the school to enhance the school mission.

- Families enrolling in the cohort portion of the project will be given a $20 gift card. Each week when they provide information, they will be entered into a drawing for a $200 gift card. They will be given an additional $20 gift card if they complete all 8 weekly reports.

The Need for Incentives

Incorporating modest incentives 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 (19). This population will be included in our respondent universe as part of our proposed school absentee monitoring system projects. Incentives 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 (20), 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 (20). 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 (21).

Level of Incentive Payment

DGMQ will not directly provide remuneration to project participants. However, during the recruitment process, partner 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 other community based partners to ensure that incentive type and value are appropriate and do not have the effect of coercing individuals to participate.

10. Assurance of Confidentiality Provided to Respondents

The information collection described in this package has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) who has determined that the Privacy act does apply. 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 partner organizations will follow procedures for securing and maintaining privacy during all stages of information collection. Participants will be recruited directly from project schools. Partner organizations 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 have 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.

IRB Approval

The protocols and tools included in this information collection request have been reviewed and approved by the IRB at Johns Hopkins University and IRB at University of Pittsburgh with CDC review and deferral to Johns Hopkins IRB. The approved protocol and approval letters from Johns Hopkins University and University of Pittsburgh and CDC's deferral approval are included in the attachments (Attachment D1– Approved Protocol, Attachment D2 - Johns Hopkins University – IRB approval, Attachment D3 - University of Pittsburgh – IRB approval, Attachment D4 - CDC IRB deferral letter, Attachment D5 – Johns Hopkins University Amendment Approval Notice).

Privacy Impact Assessment Information

1. This information collection will be implemented in collaboration with Johns Hopkins University and will target students attending kindergarten to 12th grade (K-12) schools. Johns Hopkins University through its sub-contractor, University of Pittsburgh, will implement the project in three school districts in the Pittsburgh, Pennsylvania: 1) Fox Chapel School District (3000 students in 7 schools covering K-12); 2) Propel Charter School District (3000 students in 9 schools covering K-12); and 3) Canon-MacMillan School District (5000 students in 11 schools covering K-12). (Attachment C – School District Support Letters). Information will be collected on the number, duration, and specific cause of school absences and will be obtained through telephone, in-person interviews, and through a web-based survey. Utility of these data will be assessed (using negative binomial regression, a statistical model of observed case counts of metrics of community wide influenza based upon Hidden Markov Models, temporal changes using the correlation matrix) to predict community-wide influenza transmission according to established influenza surveillance systems.

This information collection has two main components. The first is the collection of information from students, student parents/guardians (or directly from students >18 yo) related to student's absence from school because of the ILI (or if a student presented with ILI symptoms while at school), and the second collects information from a cohort of families enrolled in an active surveillance group. Both groups will be asked to provide swabs for influenza testing.

Participation in the project is determined through an active opt out process by both the parents and children of legal age. Children who are not of legal age will only participate if their parents do not opt out on their behalf, and these children will also be provided with an assent form regarding their participation. The opt-out process will be conducted each year of the project, providing all participants

the opportunity to opt out of the project in each year. Those opting out once can contact the project team to opt back in, but if families decide to opt out in any one year, they will not be contacted by the project team to participate in any following year. In order to be included in the active surveillance part of the project, potential participants must be families whose children are enrolled in one of the chosen schools in participating school districts.

Participating schools will provide name-based data on absent students during influenza season on the same day the absences occur. In two school districts, lists are electronically available on the same day, while in a third, hard copies of written lists are prepared each day. This list will be used to identify families who will be contacted by the project team in order to determine the reason for absence. To be compliant with FERPA regulations, school districts will not provide absence information on students who have been opted out of the study. All absences will be entered into a database along with the status of follow-up, including failure to follow-up or failure to contact family members. Project staff will contact the homes of individuals who do not opt out of the project. Parents of children in these schools are routinely contacted when children are absent in order to determine the cause of illness for administrative purposes. Students who experience symptoms of influenza like illness (ILI) and provide age-appropriate assent, will undergo nasal swabs for influenza (for RT-PCR analysis), in a timely and convenient manner, either at school prior to leaving school for their illness**,** or when they return to school after an absence associated with symptoms ILI. For instances when children are reported absent from school without a visit to the nurse, parents of the ill students will respond to a survey specifically intended to be conducted by telephone about their child's illness associated with an absence (Attachment H-Absentee Reporting Form: Survey of Parent or Child: Survey with Parent). If the child reports to the school nurse prior to leaving school, the nurse or study staff will use the specific script intended for use in the nurse's office in the same Absentee Reporting Form: Survey of Parent or Child: Survey with Child in Nurse Office) to ask about symptoms (Attachment D1 – Approved Protocol, page 5). The survey will take less than 5 minutes.

In order to determine the cause of respiratory illness that are not associated with school absence and assess the efficiency of existing surveillance of the larger school population, an additional cohort of up to 360 children and their household members will be enrolled into an active surveillance cohort (total sample size ~1440). The households of all participating schools will be asked if they would like to participate as cohort households. Parents and guardians in households that have not opted out will be sent a flyer to determine if they would like to participate. Cohort households will be selected on a first come, first served basis from these volunteers. If they would like to participate, parents will be asked to contact the project team to participate. Households participating in one year can also participate in the next year of surveillance but enrollment will be done independently in each year.

Household members (adults and children) in this active surveillance cohort will be asked to fill out a Cohort Intake form at enrollment (Attachment I – Cohort Intake Form) and web-based survey of their symptoms during the past week for 12 weeks of follow-up per respiratory disease season (to be filled out by parent or guardian or member over 18 in each household) to detect respiratory illness (Attachment J – Cohort Weekly Illness Report and Attachment K – screenshot of the web-based Cohort Weekly Illness Report). Each of the participants will be asked to provide information on illnesses individually to parent or guardian who will fill out the web-based form. We will encourage family members to fill the survey out together. Adults and children in the household may be asked to provide a nasal swab when another member of the household reports illness.

For the students in the 360 child sentinel cohort, nasal swabs will be obtained for any respiratory illness

that meets case definition, targeting a higher sensitivity for respiratory infection (two symptoms of either cough, runny nose, sore throat, congestion or fever plus either cough or sore throat) regardless of whether or not the illness is associated with a school absence. Nasal swabs will be obtained at the earliest time possible at the school that the cohort member attends. Nasal swabs will be obtained at the nurse's office for students enrolled in the household cohort. A self-swab kit will be delivered to the home by mail for household cohort participants who meet case definition. Participants are asked to collect a nasal swab and return this using the kit by mail to the project staff.

2. This information collection will target both, adults (through the active surveillance cohort) and children (through surveillance and sentinel cohort). Below we have outlined the information that will be collected at participating schools at one or both locations.

Information that will be gathered from parents of absent students (or students if >18 yo):

- Presence of ILI symptoms and onset time/date
- Information on whether other household members are sick
- Child's age

Information that will be gathered from sentinel cohort at the enrollment:

- Household composition (including age and gender of household members)
- Information on daycare or K-12 school (and name of the school) and aftercare for children
- Asthma and smoking of household members
- Information on regular contacts of household members

Information that will be gather from sentinel cohort weekly:

- Change in household composition
- Whether any household member got sick over the past week. For sick household members, presence of specific ILI symptoms and thermometer reading.
- Information on flu vaccine received over the past week by any household member

Information that will be collected from schools:

- Daily name-based data on absent students during influenza season. In two school districts, lists are electronically available on the same day, while in a third, hard copy of written lists are prepared each day.

3. The proposed information collection will not involve the sharing of respondent's personal identification or place of residence with persons outside of the project coordinating organizations (Johns Hopkins University, and the University of Pittsburgh as a sub-contractor). Information collected will include personal identifying information and is 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.

4. The proposed collection will not impact the respondents' privacy. All collected information will remain secure. Collected information will be entered into appropriate data management systems, and all

personal identifying information will be deleted following information verification and cleaning. Final datasets will be maintained by Johns Hopkins University. DGMQ will only have access to coded data (all links to individual identifiers will be maintained by the partner organizations). Analysis and resulting publications will not include any personal identifying information regarding participants.

5. 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.

6. The proposed information collection has been reviewed and approved by the IRBs at Johns Hopkins University and University of Pittsburgh (and CDC deferral to Johns Hopkins 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 information collection for enhanced cause-specific absentee monitoring, recruitment will rely on an opt-out letter for participation (Attachment E – Parent Opt-out Letter). Parents/guardians of students attending the participating schools will receive a letter describing the project that includes a signature section for opting-out and a full disclosure form that follows the elements informed consent. After reviewing this material, parents/guardians can choose to opt-out by signing and returning the letter. Students will provide verbal assent at the time of specimen collection. (Attachment F1a-F3b – Oral Script to Obtain Assent from Children in nurse's office or after return from absence five to six year olds, seven to 12 year olds, 13+ year olds).. In the process of making contact with the parent or child concerning their first absence, a sentence in the Survey of Parent portion of the Absentee Reporting Form: Survey of Parent or Child is included at the beginning of the script to inform the parents that they can opt-out of the study if they wish. Instructions for the individual administering the survey have also been included prior to the script to ensure that an opt-out opportunity is given if this is the first reported absence. Additionally, students and parents/guardians can opt-out at any time by simply saying that they do not wish to participate.

For the active surveillance cohort of families recruited by Johns Hopkins University, parents/guardians will consent in the following way: parents expressing interest will be given a consent form, allowed to review, sign, and provide a copy to project staff covering their household (Attachment G – SMART Cohort Consent). Using the SMART Cohort Consent form, parents will provide consent for themselves and for children under the age of 13. Household members over the age of 18, who are not parents, will also consent using the same form. Children ages 13-17 can also agree to participate in the study using this form, if they choose. Parents and students can elect to terminate participation in the project at any time.

7. All data will be stored in secured electronic files with partner organizations 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 partner organizations).

8. No system of records is being created by this information Collection. Information collected as part of this package will be covered by Privacy Act System Notice 09-20-0160 Records of Subjects in Health Promotion and Education Studies.

11. 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 a partner organization 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 Johns Hopkins University (and University of Pittsburgh as a sub-contractor) and will target students attending K-12 schools in Pittsburgh, Pennsylvania. Information will be collected on student absences for enhanced cause-specific school absentee monitoring as previously described. We provide separate burden hours and costs for sentinel family cohort portion of the project.

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 information collection for enhanced cause-specific absentee monitoring, a maximum of 2,500 students will be enrolled per year. We estimate that each student will have on average four absent episodes per year, and use the absentee reporting form (Attachment H – Absentee Reporting Form: Survey of Parent or Child) – one for each of these absences. Johns Hopkins University staff estimates that it will take less than 5 minutes to complete the relevant portion of the Absentee Reporting Form: Survey of Parent or Child for each instance when there is an absence. The survey may be completed over the telephone with the parent if the student is not present at the school (Survey with Parent), or may also be done in-person with the student if the student is present at school at time of illness and is in the nurse's office (Survey with Child in Nurse Office). It is also estimated that assent and specimen collection at school will take less than 5 minutes to complete. The burden for project participants in the enhanced ILI-specific monitoring portion of the project is estimated at 1,665 hours.

The project will also enroll a sentinel cohort of 360 student families. These families will be requested to complete a survey to report symptoms related to possible acute respiratory infections on a weekly basis

for a total of 12 weeks. The one-time questionnaire (Attachment I - Cohort Intake form) will require no more than 10 minutes to complete, for 60 total burden hours. The weekly survey can be completed in 3 minutes (Attachment J – Cohort Weekly Illness Report). Specimen collected will be done from all sick household members (~1,440) through self-swab, which will take less than 5 minutes per person. These families may or may not participate in the enhanced cause-specific absentee monitoring portion of the project. The burden for the sentinel cohort of family survey is estimated at 396 hours.

The total burden for project participants is estimated at 2,062 hours.

Table A.12-A: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Parents of children/adolescents attending schools	Absentee Reporting Form: Survey with Parent	1,250	4	5/60	416
Children/adolescents attending schools	Absentee Reporting Form: Survey with Child in Nurse Office	1,250	4	5/60	416
Assent and biospecimen collection from students (absentee surveillance)	Age-appropriate Oral Script to Obtain Assent from Children (After return from absence or Nurse Office)	2,500	4	5/60	833
Sentinel Family Cohort	Cohort Intake	360	1	10/60	60
Sentinel Family Cohort	Cohort Weekly Illness Report	360	12	3/60	216
Biospecimen collection from sentinel cohort (students and household members)	SMART Cohort Consent Form*	1,440	1	5/60	120
TOTAL		7,160			2,062

*Consent for parents and children under 13 is given by the parents; non-married adults can also provide consent; children 13-17 can also agree to participate by signing, if they chose. This is a once yearly consent process and parents may choose to opt out at any time. The only information accompanying the bio-specimen collection is in the Cohort Weekly Illness Report.

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 2011 National Occupational Employment and Wage Estimates for the United States (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). An average hourly salary of approximately $22.33 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 1,109 the overall cost of participants' time for the example information collections is estimated to be a maximum of $46,045 (2,062 hours * $22.33 per hour).

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

Table A.12-B: Estimated Annualized Burden Costs.

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Parents of children/adolescents attending schools	Absentee Reporting Form: Survey with Parent	416	$22.33	$9,289
Children/ adolescents attending schools	Absentee Reporting Form: Survey with Child in Nurse Office	416	$22.33	$9,289
Assent and biospecimen collection from students (absentee surveillance)	Age-appropriate Oral Script to Obtain Assent from Children (After return from absence or Nurse Office)	833	$22.33	$18,601
Sentinel Family Cohort	Cohort intake	60	$22.33	$1,340
Sentinel Family Cohort	Cohort Weekly Illness Reporting	216	$22.33	$4,823
Biospecimen collection from sentinel cohort (students and household members)	SMART Cohort Consent Form	120	$22.33	2,680
TOTAL		2,062		$46,022

*Public wages from http://www.bls.gov/oes/current/oes_nat.htm#00-0000

13. Estimates of Other Total Annual Cost Burden to Respondents or 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 costs. The only cost to the federal government would be the salary of CDC staff supporting the data 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 at $120,000/year)	$36,000
Contractual costs for an information collection (e.g. facility rental, moderator/interviewer, participant recruitment, translations, transcriptions and final reports) -School absentee project = $500,000/year	$500,000
Cost per information collection	$536,000
Total cost for annualized information collections	$536,000

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

In collaboration with the partner organizations, DGMQ intends to publish the results from this information collection. Results will be presented at professional conferences and in peer-reviewed journals. In collaboration with Johns Hopkins University, DGMQ anticipates starting the project in Pittsburgh, PA in April 2015. 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.

REFERENCES

1. Kilbourne ED. Influenza pandemics of the 20th century. *Emerg Infect Dis* 2006;12 (1):9-14.

2. Leung GM, Nicoll A. Reflections on pandemic (H1N1) 2009 and the international response. *PLoS Med* 2010; 7(10):1-6.

3. Department of Health and Human Services. Guidance on Allocating and Targeting Pandemic Influenza Vaccine. Available at http://www.pandemicflu.gov/vaccine/allocationguidance.pdf. Accessed on August 21, 2013.

4. DiMenna LJ, Ertl HCJ. Pandemic Influenza Viruses. In: Compans, RW, Orenstein WA, eds. Vaccines for Pandemic Influenza. Berlin (Germany): Springer; 2009.

5. Schwartz B, Ornstein WA. Prioritization of Pandemic Influenza Vaccine: Rationale and Strategy for Decision-Making. In: Compans, RW, Orenstein WA, eds. Vaccines for Pandemic Influenza. Berlin (Germany): Springer; 2009.

6. CDC. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza: Recommendations of the ACIP. *MMWR* 2011; 60:1-24.

7. Centers for Disease Control and Prevention. Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States-Early, Targeted, Layered Use of Non-Pharmaceutical Interventions, February 2007. Available from: http://www.flu.gov/planning-preparedness/community/community_mitigation.pdf. Accessed April 4, 2013.

8. Viboud C, Boelle PY, Cauchemez S, Lavenu A, Valleron AJ, Flahault A, et al. Risk factors of influenza transmission in households. Br J Gen Pract. 2004 Sep;54(506):684-9.

9. Longini IM, Jr., Koopman JS, Monto AS, Fox JP. Estimating household and community transmission parameters for influenza. Am J Epidemiol. 1982 May;115(5):736-51.

10. Davis LE, Caldwell GG, Lynch RE, Bailey RE, Chin TD. Hong Kong influenza: the epidemiologic features of a high school family study analyzed and compared with a similar study during the 1957 Asian influenza epidemic. Am J Epidemiol. 1970 Oct;92(4):240-7.

11. Dennis L. Chao, M. Elizabeth Halloran, and Ira M. Longini, Jr,2School Opening Dates Predict Pandemic Influenza A(H1N1) Outbreaks in the United States. JID 2010:202 (15 September)

12. Besculides M, Heffernan R, Mostashari F, Weiss D. Evaluation of school absenteeism data for early outbreak detection, New York City. BMC Public Health. 2005;5:105. http://dx.doi.org/10.1186/1471-2458-5-105

13. Rodriguez D, Zhang G, Leguen F, O'Connell E, Bustamante M. Using public school absentee data to enhance syndromic surveillance in Miami-Dade County, 2007. Advances in Disease Surveillance. 2007;4:188.

14. Rodriguez CV, Rietberg K, Baer A, Kwan-Gett T, Duchin J. Association between school closure and subsequent absenteeism during a seasonal influenza epidemic. Epidemiology. 2009;20:787–92. http://dx.doi.org/10.1097/EDE.0b013e3181b5f3ec

15. L. Tan, L. Cheng, W. Yan, J. et al. Using daily syndrome-specific absence data for early detection of school outbreaks: a pilot study in rural China. Public Health. 128 (2014) 792e798.

16. Calvin K. Y. Cheng1, Hing Channarith2, Benjamin J. Cowling. Potential Use of School Absenteeism Record for Disease Surveillance in Developing Countries, Case Study in Rural Cambodia. PLoS One. October 2013 | Volume 8 | Issue 10 | e76859.

17. Yunzhou Fan, Mei Yang, Hongbo Jiang et al. Estimating the Effectiveness of Early Control Measures through School Absenteeism Surveillance in Observed Outbreaks at Rural Schools in Hubei, China. PLoS One. September 2014, Volume 9, Issue 9, e106856.

18. Joseph R. Egger, Anne G. Hoen, John S. Brownstein, David L. Buckeridge, Donald R. Olson, Kevin J. Konty. Usefulness of School Absenteeism Data for Predicting Influenza Outbreaks, United States. Letter to Editor. Emerging Infectious Diseases. Vol. 18, No. 8, August 2012

19. Mosher, W., *Design and operation of the 1995 National Survey of Family Growth.* Family Planning Perspectives, 1998. **30**(1).

20. Berlin, M., et al. An experiment in monetary incentives, in Proceedings of the American Statistical Association Section on Survey Research Methods. A.S. Association, Editor 1992, American Statistical Association: Alexandria, Virginia. p. 393-398.

21. Krueger, R. Focus groups: A practical guide for applied research. 2nd ed1994, ThousandOaks, California: Sage Publications.

ATTACHMENTS

A1. Section 361 of the Public Health Service (PHS) 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

C. School district support letter

D1. Approved Protocol

D2. Johns Hopkins University – IRB approval

D3. University of Pittsburgh – IRB approval

D4. CDC IRB deferral letter

D5. Johns Hopkins University Amendment Approval Notice

E. Parent letter (opt-out form)

F1a. Oral Script to Obtain Assent from Children 5 to 6 year olds - After return from absence

F1b. Oral Script to Obtain Assent from Children 5 to 6 year olds - Nurse Office

F2a. Oral Script to Obtain Assent from Children 7-12 years old - After return from absence

F2b. Oral Script to Obtain Assent from Children 7-12 years old - Nurse Office

F3a. Oral Script to Obtain Assent from Children 13 years old and older - After return from absence

F3b. Oral Script to Obtain Assent from Children 13 years old and older - Nurse Office

G. SMART Cohort Consent form

H. Absentee Reporting Form: Survey of Parents or Child

I. Cohort Intake form

J. Cohort Weekly Illness Report

K. Cohort Weekly Illness Report screenshot

L. Non-substantive Comment from Jean Public