JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

FWA #00000287

Institutional Review Board Office

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INITIAL APPLICATION APPROVAL NOTICE

Date: August 29, 2014

To: Derek Cummings, PhD
Department of Epidemiology

From: Luke C. Mullany, PhD, MHS
Chair, IRB-X

Re: **Study Title**: "Monitoring Cause Specific Absences to Estimate Influenza Transmission"
IRB No: 00005474

The **JHSPH IRB-X** voted to approve the above referenced application at its meeting on **August 21, 2014**. **The Board made the following determinations:**

Approval of the research is for the period of **August 21, 2014** to **August 20, 2015** **Please submit a progress report no later than 6 weeks before the approval lapse date. We recommend that YOU USE YOUR OUTLOOK CALENDAR, OR OTHER ELECTRONIC REMINDER CALENDAR TOOL, to set a timely reminder notification for this submission to avoid a lapse in approval.**

Single Reviewer ☐ **Convened** ☒ DHHS 46.110 . . ☒ DHHS..... ☐ FDA 56.110 . . . ☐ FDA..... ☐ Category: 3, 5, & 7 **GWAS** ..... ☐	**Consent/Parental Permission Required From:** Adult Participant ..... ☒ LAR ..... ☐ One Parent ..... ☒ Two Parents..... ☐ Legal Guardian ..... ☐ (Foster Care Children)	**Form of Consent/Permission:** Written Consent..... ☒ Waiver of Signature..... ☒ (Oral Script) Waiver of Informed Consent.... ☐ HIPAA Authorization..... ☐ HIPAA Waiver..... ☐ No Longer Enrolling..... ☐	**Study Site(s):** U.S. ☒ International ☐ **List Country(ies):**
Vulnerable Populations: Children ..... ☒ Foster Care Children ..... ☐	**Assent Required From:** No children (waived) . ... ☐ Children aged: 5 – 13+ ☒	**Pregnant Women/Fetuses** 46.204 ..... ☐ **Neonates** 46.205 ..... ☐	**Sample Size:** (screened plus enrolled) **11,000** **Final Enrollment:**

DHHS	FDA	Form of Assent:	Prisoners	
46.404 . . . . ☒	50.51 ..... ☐	Written ..... ☐	46.305 ..... ☐	**Secondary Data Analysis**:
46.405. . . . ☐	50.52 ..... ☐	Oral ..... ☐	46.306 ..... ☐	(# specimens/participants)
46.406 . . . . ☐	50.53 ..... ☐	Assent Statement in Parent Permission ..... ☐	Epidemiological Research.... ☐	

This approval is inclusive of the following documentation:

Research Plan (Version #1, 8-27-14)

Consent Form (Version #1, 8-21-14)

Disclosure Document (Version #1, 8-21-14)

Parental Permission: Opt Out Letter (Version #1, 8-21-14)

Oral Assent Script to Obtain Assent from Children 5-6 (Version #1, 8-21-14)

Oral Assent Script to Obtain Assent from Children 7-12 (Version #1, 8-21-14)

Power Point Presentation to Students Parents Teachers Group (Version #1, 8-21-14)

Recruitment Flyer (Version #11, 8-29-14)

Study Flyer (Version #11, 8-29-14)

End of Year Questionnaire (Version #11, 8-29-14)

Enrollment Form (Version #11, 8-29-14)

Illness Questionnaire Illness Report (Version #11, 8-29-14)

As principal investigator of the research, you are responsible for fulfilling the following requirements of approval:

1) The co-investigators listed on the application should be kept informed of the status of the research.
2) Submit an Amendment Request Form for any changes in research. These changes in research are required to be reviewed and approved prior to the activation of the changes, with the following exceptions:
    a) changes made to eliminate an apparent immediate hazard to the research participant may be instituted immediately and the JHSPH IRB should be informed of such changes promptly; and
    b) changes to IRB Approved questionnaires, interview or focus group guides, other data collection or recruitment materials – limited to rewording to clarify meaning, correcting grammatical or typographical errors, or removing items that will not be used in the research.

3) Unanticipated problems involving risk of harm to participants or others that are related to the study procedures must be reported to the JHSPH IRB within 10 days of the time that the PI learns of such problems**.** A Problem Event Report Form must be submitted to the IRB immediately.

4) Only consent forms with a valid JHSPH IRB approval stamp or logo, with the correct IRB Approved version number and approval date may be presented to participants. All consent forms signed by subjects enrolled in the study should be retained on file. The Office of Graduate Education and Research conducts periodic compliance monitoring of study records, and consent documentation is part of such monitoring.

5) Federal regulations require review of approved research not less than once a year, unless a shorter period is determined by the IRB. **Therefore, a Progress Report for continuing review must be submitted to the IRB Office no later than six weeks prior to the approval lapse date**. **This will allow sufficient time for review of the application to be completed prior to the approval lapse date**. Failure to submit a Progress Report prior to the approval lapse date will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must discontinue participation in the study. All ongoing research activities must stop immediately, including data analysis.

6) If your research involves international travel, please don't forget to register with the International Travel Registry https://apps4.jhsph.edu/ITR/Default.aspx so that the School may locate you in the event of an emergency.

LCM/sro