

Institutional Review Board Office

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AMENDMENT APPROVAL NOTICE

Date: March 20, 2015

To: Derek Cummings, PhD
Department of Epidemiology

From: Elizabeth A. Skinner, MSW
Acting Chair, IRB-X

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

The JHSPH IRB-X reviewed and approved the amendment request described below, and received by the JHSPH IRB Office on **March 16, 2015**, at its meeting on **March 19, 2015**.

<p>Single Reviewer <input checked="" type="checkbox"/> Convened <input type="checkbox"/></p> <p>DHHS 46.110 .. <input checked="" type="checkbox"/> DHHS.....<input type="checkbox"/> FDA 56.110 ... <input type="checkbox"/> FDA.....<input type="checkbox"/></p> <p>Category: 3, 5 & 7</p>	<p>Consent/Parental Permission Required From:</p> <p>Adult Participant.....<input checked="" type="checkbox"/> LAR<input type="checkbox"/> One Parent.....<input checked="" type="checkbox"/> Two Parents<input type="checkbox"/> Legal Guardian.....<input type="checkbox"/> (Foster Care Children)</p>	<p>Form of Consent/Permission:</p> <p>Written Consent.....<input checked="" type="checkbox"/> Waiver of Signature.....<input checked="" type="checkbox"/> (Oral Script) Waiver of Informed Consent....<input type="checkbox"/> HIPAA Authorization.....<input type="checkbox"/> HIPAA Waiver.....<input type="checkbox"/> No Longer Enrolling.....<input type="checkbox"/></p>	<p>Study Site(s):</p> <p>U.S. <input checked="" type="checkbox"/> International <input type="checkbox"/></p> <p>List Country(ies):</p>
<p>GWAS.....<input type="checkbox"/></p>	<p>Assent Required From:</p> <p>No children (waived) ... <input type="checkbox"/> Children aged: 5-13.....<input checked="" type="checkbox"/></p> <p>Form of Assent:</p> <p>Written<input type="checkbox"/> Oral<input checked="" type="checkbox"/> Assent Statement in Parent Permission<input type="checkbox"/></p>	<p>Pregnant Women/Fetuses</p> <p>46.204.....<input type="checkbox"/></p> <p>Neonates</p> <p>46.205<input type="checkbox"/></p> <p>Prisoners</p> <p>46.305<input type="checkbox"/> 46.306<input type="checkbox"/> Epidemiological Research...<input type="checkbox"/></p>	<p>Sample Size: (screened plus enrolled)</p> <p>11,000</p> <p>Final Enrollment:</p> <p>Secondary Data Analysis: (# specimens/participants)</p>
<p>Vulnerable Populations:</p> <p>Children<input checked="" type="checkbox"/> Foster Care Children<input type="checkbox"/></p> <p>DHHS FDA</p> <p>46.404 . . . <input checked="" type="checkbox"/> 50.51.....<input type="checkbox"/> 46.405. . . <input type="checkbox"/> 50.52.....<input type="checkbox"/> 46.406 . . . <input type="checkbox"/> 50.53.....<input type="checkbox"/></p>			

This amendment approval is for the following revisions to the above referenced study:

- 1). To include the use of two different assent scripts for children; one for children who are reporting to the nurse's office ill and the other for children who are reporting to the nurses office after return from an absence due to illness.**
- 2). To include minor edits to the "Illness Questionnaire Illness Report" based on feedback from the Office of Management Budget.**

and is inclusive of the following revised or newly submitted documentation:

Research Plan (Version #2, 3-15-15)

Absentee Reporting Form (Version #11, 8-29-14)

Surveillance, Monitoring Absenteeism and Respiratory Transmission in Schools Consent Form (Version #2, 3-19-15)

Oral Script to Obtain Assent Form Children 5-6 (After Return to School from Absence) (Version #1, 3-19-15)

Oral Script to Obtain Assent from Children 5-6 (In Nurse's Office) (Version #1, 3-19-15)

Oral Script to Obtain Assent form Children 7-12 (After Return from Absence) (Version #1, 3-19-15)

Oral Script to Obtain Assent form Children 7-12 (In Nurse Office) (Version #1, 3-19-15)

Oral Script to Obtain Assent form Children 13 (After Return from Absence) (Version #1, 3-19-15)

Oral Script to Obtain Assent from Children 13 (In Nurse Office) (Version #1, 3-19-15)

As a reminder, no other changes to this study may be implemented without prior JHSPH IRB review and approval.

The action taken on this study does not change the IRB expiration date, which remains **August 20, 2015**.

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.

If you have any questions regarding this action, please contact the JHSPH IRB Office at (410) 955-3193 or via email at jhsph.irboffice@jhu.edu

EAS/sro