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PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	7 Mar 2019
TO:	Erin Maughan, PhD, RN National Association of School Nurses
PROTOCOL:	Centers for Disease Control and Prevention (Contract to NASN), Feasibility Evaluation of a School Nurse Led Active Surveillance Process (Pro00032437)
APPROVAL DATE:	5 Mar 2019

IRB APPROVED DOCUMENTATION:

Protocol Versions:

- Feasibility Evaluation of a School Nurse Led Active Surveillance Process (Dated: 3/1/19)
- School Nursing Reporting Worksheet for Process Feasibility Evaluation (Dated: 3/1/2019)
- National Data Platform Feasibility and Data Points (Dated: 2/14/19)
- School Nurse-Led Chronic Absenteeism Surveillance Process (Dated: 2/14/19)

Consent Forms:

- Consent Form and Authorization for School District Representatives (Advarra IRB Approved Version 05 Mar 2019)
- Consent Form and Authorization for School Nurses (Advarra IRB Approved Version 05 Mar 2019)

Recruitment Material:

- Feasibility Evaluation of a School Nurse Led Active Surveillance Process (Dated: 2/14/19)

The IRB approved the above referenced protocol and your site with the modifications listed below on 5 Mar 2019:

- **Modification to the Consent Form and Authorization for School District Representatives**
- **Modification to the Consent Form and Authorization for School Nurses**

If you wish to have the IRB reconsider the imposed modifications, you may follow the procedures outlined below:

1. Submit supporting documentation that addresses the IRB's concerns.
2. Provide a written justification for relief of any IRB imposed condition.

The IRB reviewed the project in accordance with the 45 CFR Part 46, Subpart D Federal Regulations which provide for additional protections for children as research subjects.

The IRB determined that the research study meets the criteria found in the risk category described as follows:

- 45 CFR 46.404 *"Research not involving greater than minimal risk." Waiver of Parental Consent.*

The above referenced recruitment material is available on your Advarra CIRBI Platform under the "IRB Issued Documents" tab.

If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

There is no expiration date for this study and it is not subject to requirements for continuing review under the revised Common Rule (2018 Requirements). However, a termination report must be submitted upon termination of the study.

Approved investigators and sites are required to submit to Advarra for review, and await a response prior to implementing, any amendments or changes in: the protocol; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Please review the IRB Handbook located in the "Reference Materials" section of Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.

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