Attachment J

Consent Form and Authorization for School Nurses

Sponsor / Study Title:	**Centers for Disease Control and Prevention / "Centers for Disease Control and Prevention / "School-Based Active Surveillance (SBAS) of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Among Schoolchildren: Phase-2 of the National Roll-Out**
Principal Investigator:	**Andrea Tanner, PhD, RN, NCSN**
Telephone:	**(240) 247-1624 (24 Hours)**
Address:	**National Association of School Nurses** **1100 Wayne Ave, Suite 925** **Silver Spring MD 20910**

KEY INFORMATION

This study is to evaluate the feasibility of exapanding a surveillance process for chronic absenteeism is being conducted by Andrea Tanner, PhD, RN, NCSN with the National Association of School Nurses (NASN). Students who are chronically absent or withdraw from school due to health concerns is a growing concern across the country.

- Common health conditions include chronic conditions (i.e. asthma, diabetes, depression), social determinants of health, and undiagnosed conditions whose symptoms make it difficult to attend school (Healthy Schools Campaign, 2016).
- It has been thought that myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) may account for a high proportion of students with overwhelming fatigue and dizziness that lead to students being chronically absent or even school withdrawal.
- School nurses (SNs) are at the frontlines of student health. They already use their nursing expertise and proximity to vulnerable students, to proactively identify and document student health concerns and assist families in getting the care that they need.
- The purpose of this project is to evaluate a process to guide school nurses in the identification and management of students who are chronically absent for health concerns, with particular emphasis on students who may be at risk for ME/CFS.
- The process includes school nurses obtaining a list of students who are chronically absent or officially withdrawn from school due to health reasons. School nurses will then reach out to these students and their families using some guided questions to identify the health concerns and determine if the students may be at risk for ME/CFS. The school nurse will use the information to identify ways to assist in addressing the

health issues so that student can return to school. De-identified, combined data will be then be submitted to a national data platform.
- By conducting the process in your district, you the school nurse will have an opportunity to address the needs of students who are chronically absent so that the students can get the assistance they need in order to return to school.
- Conducting the process allows you to influence the creation of a manual to help other school districts to track and identify students.
- Conducting the process will take time that you would have used for other activities, and may necessitate changing in how you track students for health reasons.

Please read this form carefully. Take your time to ask as many questions about the project as you would like. If you decide to take part in this project, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You were selected to participate in this study because you were selected by your district who has agreed to be part of this evaluation, your main assignment in school nursing is with the general student population, and you work in a school that has students who are chronically absent or withdrawn from school due to health concerns. The purpose of this research study is:
- To test the feasibility of expanding a school nurse led surveillance process to identify students who are chronically absent or withdrawn from school due to health concerns; and
- Evaluate the usability of a national data platform.

About 24 states will be enrolled in this study. From those districts up to 60school nurses may be asked to participate.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately 3 years. The time it takes to participate in this project will depend on the number of students who are chronically absent and the complexity of their situation. Submission of data and reporting worksheets will take approximately 20-30 minutes to complete.

Throughout the study the following procedures will be followed:
- Before participation of the districts can begin the participants must sign and date the informed consent.
- Identify students who are chronically absent
- Identify students who are chronically absent for health reason (or suspected to be health reasons).
- Outreach to students and their families
- Identify reason(s) for absences/withdrawal
- Initiate care coordination and continue nursing process (and work with other school staff as appropriate
- Develop nursing plan for each chronically absent student.

- Evaluate care plan (at time interval determined in care plan)
- Submit data to national platform
- Evaluate overall process
    - At the end of each year the district and research team will discuss and decide together if the surveillance process will be expanded to include additional school nurses (or schools) in the district
- Every other month during the school year you will participate in a phone call with school nurses from other districts who are conducting the process as well.
    - Each call will be less than an hour and be used to answer questions or clarify the process.

This study will require you to travel in the first and second years of the study. To participate in face to face training of the process with NASN investigators and focus groups at the NASN annual conferences.

EXPECTATIONS
Participation in this project includes assisting your district in completing an assessment of what you and your district currently do related to chronic absenteeism. The assessment information will help NASN during a face to face training when we review the surveillance process that you will follow, and the information to be collected and submitted. You will then follow the surveillance process for the three year time period . At the end of each school year (as well as a mid-year check during year 2) you will provide written feedback on your experience, as well as participate in face to face focus groups with other school districts participating in the process . In addition, you will share combined, de-identified data on the process followed. The data will be used for updating the questions and suggested data school nurses would collect when following the process.

To evaluate the usability of the data platform, you will also submit combined, de-identified data related to the number of students with chronic conditions, chronic absenteeism, school health workforce, and health office visits to test the national data platform.

RISKS
No other foreseeable risks of discomforts to the participants are expected. No personally identified health information will be collected for the study.

ALTERNATIVES TO PARTICIPATION
This study is for research purposes only. The only alternative is to not participate in this study.

BENEFITS
The direct benefit for you participating in this project is increased knowledge regarding how to track and address the needs of students who are chronically absent or have withdrawn from school due to health reasons. In addition, the experience may help other school nurses because the information gained from this evaluation will be utilized in tweaking the process for a

national guidance manual other districts may follow. Any new important information that is discovered during the feasibility testing will be shared with your district.

COMPENSATION FOR PARTICIPATION

The district will be paid $2000 each year the district participates in conducting the surveillance process and submitting data into the national platform (for a total of $6000 over 3 years). How this money will be used will be decided internally by the district. In addition, costs for travel and lodging for you to participate in face to face focus groups at the first NASN annual conference up to $1080.00 and the second NASN annual conference up to $930.00 will be covered by NASN. Travel expenses will be paid for upfront as much as possible; reimbursements for any costs not able to be paid upfront will be provided within 30 days of receipts. If you have any questions regarding your compensation for participation, please contact your district.

CONFIDENTIALITY

All data will be provided in de-identified, combined form. Information provided in the reporting worksheets and focus groups regarding the surveillance process will remain confidential and will only be reported as group data with no identifying information. The information will be kept on a password protected, secure computer server. The information collected from the face-to-face meetings, will be kept in a locked storage cabinet and only those directly involved with the research will have access to them. After the research is completed, the notes will be destroyed.

The de-identified, data submitted to the national data platform will not be reported out except in combined form with other district participating. However, if the number is smaller than 7 the number will not be reported. Information on the national data platform includes you and your school's names. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the Department of Health and Human Services and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. This information will only be seen by the research team and will not be used in any reports or made public. If your district decides to be listed as a demonstration sites in the guidance manual, you will have the option to decide if you would like your name listed as a participating nurse or if you would prefer to stay anonymous.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights and/or concerns or complaints regarding this evaluation study, contact**:**

- By mail:

  Study Subject Adviser

Advarra IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00032437.

VOLUNTARY PARTICIPATION / WITHDRAWAL

You and your district's decision to participate in this evaluation is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty, loss of benefits, or to your employment in the district or any future involvement with NASN. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study.

NASN or the sponsor, can stop you or your district's participation at any time without your consent for the following reasons:

- If you or your district fails to follow directions for participating in the study;
- If the study is canceled; or
- For administrative reasons.

FUNDING

This project was funded through contract by the Centers for Disease Control and Prevention to the National Association of School Nurses (75D301-18-R-67839.)

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to have the district participate in this evaluation until I decide otherwise. I do not give up any of my district's legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

School Nurse's Printed Name

_____ _____

School Nurse's Signature Date

_____

Printed Name of NASN representative

_____ _____

Signature of NASN representative Date