

Attachment I

Consent Form and Authorization for School District Representatives

Sponsor / Study Title: 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 expanding 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- The process includes school nurses obtaining a list of students who are chronically absent or officially withdrawn from school due to health reasons.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 then be submitted to a national data platform.

- By conducting the process in your district, school nurses and other district staff 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 your district to influence the creation of a manual to help other school districts to track and identify students.
- Conducting the process will take time that school nurses and others have used for other activities, and changes may be needed to be made in your student tracking system to better identify students chronically absent for health reasons.

Please read this form carefully. Take your time to ask as many questions about the study 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

Your district was selected to participate because you have students who are chronically absent or withdrawn from school due to health reasons. The purpose of this research study is:

- To test the possibility of 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 60 school nurses may be asked to participate. School nurses will be asked to sign a separate consent form.

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 and the current system used in the district to track students who are chronically absent. Submission of feedback should take 5-10 minutes.

Throughout the study the following procedures will be followed:

- Districts will identify potential school nurses to participate in the research study.
- Before participation in the research study a district representative must sign and date the informed consent.

During this study, the identified school nurses will do the following:

- Sign and date a separate informed consent form
- 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.

This study will require the school nurses 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 completing an assessment of what your district currently does related to chronic absenteeism. The assessment information will help NASN during a face to face training when we review the surveillance process school nurses will follow, and the information to be collected and submitted. District responsibilities will include supporting a way to track students who are chronically absent for health reasons and providing the information to participating school nurses. This may involve changing your current electronic tracking system. The district will select the school nurses who participate; and will allow participating school nurses to attend the face to face interviews. Finally, districts will provide support in addressing chronic absenteeism at a district level and provide feedback (either by email or by phone) on the process from a district level. The information gathered from the district and school nurse will be used for updating the questions and suggested data school nurses will collect when following the process.

RISKS

No other foreseeable risks of discomforts to the participants are expected. No personally identified health information will be collected. Although all data will be de-identified, there may be a risk of loss of privacy and confidentiality. There may be other risks that are unknown.

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 the district 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 will help other school districts because the information gained from this evaluation will be utilized in adjusting the process for a national guidance manual other districts may follow. Any new important information that is discovered during the testing will be shared with your district.

COMPENSATION FOR PARTICIPATION

The district will be paid \$2000 each year the district participates in the research study (for a total of \$6000 over 3 years). The district will receive the yearly compensation after the reporting worksheet and data has been submitted at the end of each school year. Partial compensation will not be given if a district decides to withdraw during a school year. In addition, costs for travel and lodging for the school nurse at 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 NASN project staff.

COSTS

There will be no charge to you for your participation in this study.

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 of school nurses, 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 the name of the nurses and schools. 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. You will have the option of having the name of your district listed as a demonstration site in the guidance manual.

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:
Pro00059494.

VOLUNTARY PARTICIPATION / WITHDRAWAL

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 or loss of benefits to which you are otherwise entitled. 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 your district's participation at any time without your consent for the following reasons:

- If 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 (75D30121C12121.)

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.

District Representative's Printed Name

District Representative's Signature

Date

Printed Name of NASN representative

Signature of NASN representative

Date