Initial Submission Approved for #2020B0252

Sent Date

10/08/2020 9:13 am

From

Ryan Liersemann <liersemann.1@osu.edu>

To

Shayne Piasta <piasta.1@osu.edu>

Cc

Naomi Schneider <schneider.572@osu.edu>
Ryan Liersemann <liersemann.1@osu.edu>

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

10/08/2020

Study Number: 2020B0252
Study Title: Translating research into school-based practice via small-group, language-focused comprehension intervention

Type of Review: Initial Submission

Review Method: Expedited

Date of IRB Approval: 10/08/2020
Date of IRB Approval Expiration: 10/08/2021

Expedited category: #5, #6, #7

Dear Shayne Piasta,

The Ohio State Behavioral and Social Sciences IRB **APPROVED** the above referenced research.

In addition, the following were also approved for this study:

- Children
- Waiver of Consent Documentation

Administrative Note:

- As the university moves to a staged approach to restarting research activities, refer to Human Subjects Guidance and FAQs. If after reviewing this information and working through your college you have additional questions, please direct emails to research@osu.edu.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, a continuing review application must be approved before the expiration date to avoid a lapse in IRB approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.

Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

Annual Status Report Confirmed for #2020B0252

Sent Date

08/25/2022 12:10 pm

From

Corey Spring <spring.45@osu.edu>

To

Shayne Piasta <piasta.1@osu.edu>

Cc

Jill Twersky <twersky.3@osu.edu>

Office of Responsible Research Practices

300 Research Administration building
1960 Kenny Road
Columbus, OH 43210-1063

orrp.osu.edu

08/25/2022

Study Number: 2020B0252
Study Title: Translating research into school-based practice via small-group, language-focused comprehension intervention

Type of Review: Annual Status Report

Date of Annual Status Report Confirmation: 08/25/2022
Date of IRB Approval Expiration: 08/25/2023

Dear Shayne Piasta,

The Office of Responsible Research Practices has **CONFIRMED CONTINUATION** of the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This confirmation is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, an annual status report or continuing review application must be approved before the expiration date to avoid a lapse in approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.

Human research protection program policies, procedures, and guidance can be found on the ORRP website.

IRB Protocol Number:
IRB Approval date:
Version:

Assent to Participate in Research
Verbal Script and Research Staff Documentation

Study Title: Translating research into school-based practice via small-group, language-focused comprehension intervention
Investigators: Shayne Piasta, Tiffany Hogan, Mindy Bridges, Kandace Fleming
Sponsor: National Institutes of Health

Read the following to the child:
We are working with your school on a research study. Studies are done to find better ways to help people or to understand things better. We want to learn how to help children to understand what they read and hear.

If you are in this study, you will come with us to answer questions so we can learn what you know about reading and listening. Some children will meet with us each week during Grade 1 to learn new things – you will read different books and do different activities with some other children. Some children will stay in their classrooms. We will meet with you again a few times when you are older to see what you have learned.

It is okay to say "No" if you don't want to be in the study. You won't get in trouble.

Do you want to be in our study?

Completed by investigator/researcher staff

I have explained the research to the following child participant:

_____	_____
Printed name of child	Date and time

The child DID / DID NOT assent (circle one).

_____	OSU / MGH
Printed name of person obtaining assent	(circle research site)
_____	_____
Signature of person obtaining assent	Date and time

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.

Let's Know!2 – Opportunity for Supplemental Language and Comprehension Intervention

Researchers at The Ohio State University, MGH Institute of Health Professions, and University of Kansas/University of Kansas Medical Center have partnered with your child's school to study the *Let's Know!* intervention. This intervention provides supplemental early language and reading comprehension instruction to young children who may need extra support in these areas. We are studying children's language and literacy development from Grade 1 through the elementary years and whether *Let's Know*! better prepares children for later language and reading success. Several children in your child's school will be selected to experience the *Let's Know*! intervention and/or contribute data to this research study. This document provides information about the research study and seeks consent for you and your child to participate.

What You and Your Child Will Do

Participation in the research study is voluntary and open to children currently enrolled in Grade 1. Your child will continue to receive regular instruction as provided by their classroom teacher. If you consent to participate in the study, you will complete the attached survey (requiring approximately 15 min) and your child's teacher will also complete a brief survey. You may refuse to answer any survey questions without penalty. If you provide consent and your child qualifies:

- We will screen your child's language in the fall of Grade 1 with a small group of children or one-on-one. This will take about 10 minutes. Children will be invited to participate in the study based on their need for extra support.
- If your child is selected to participate, we will assess your child's language and literacy skills in the fall and spring of Grade 1 and once in Grade 2 and in Grade 3. These assessments will be conducted at your child's school and will be administered by our highly trained research staff. Total assessment time at each time point is a maximum of 2.5 hrs, and will be conducted in multiple, short sessions. Participants will also receive four 15-minute progress monitoring assessments in Grade 1. Assessments may be audio recorded. With your permission, we will share assessment results with your child's teacher/school.
- Your child may be selected to receive *Let's Know*! lessons in a small group of 3-5 children. Lessons will occur four times a week for 22 weeks during Grade 1. These lessons will be provided by research staff in a quiet space at your child's school during the school day. Lessons will be videotaped so we can better understand how the program works. If your child is not chosen to receive these lessons, your child will continue to receive regular instruction in their classroom.
- We will obtain your child's state Third Grade English Language Arts scores when your child is in Grade 3. We will obtain your child's state student identification number to get these scores; you do not need to provide them.

If you consent for your child to participate in the research and your child is selected, you will receive a $25 incentive after your child completes assessments in Grade 2 and Grade 3. Your child will also receive small incentives (e.g., stickers) when they work with our staff.

Risks and Benefits

As reviewed and approved by the OSU Institutional Review Board, risks associated with participation in this research are not greater than those ordinarily encountered in daily life. Efforts will be made to keep your child's study-related information confidential. Children may participate in small groups, such that their peers will be aware of their participation and responses during sessions. Identifiable data will be stored on university (OSU, MGHIHP, KU/KUMC) servers and analyzed by investigators at these institutions. Because this is a federally funded study, non-identifiable research data may be used or shared with other researchers for research purposes only. Also, information may be disclosed if required by state law and may be reviewed by the following (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study.

You may refuse or discontinue participation in the research at any time without penalty or loss of benefits to which you are otherwise entitled. We may share a copy of this consent form with your child's school to show your willingness to participate and permission to work with your child.

Confidentiality
The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information and documents. The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations. Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions. You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Questions and Concerns
If you have questions or concerns about the research, you may contact the OSU Project Coordinator, [Insert Project Coordinator Name] (insert phone number; insert email address) or Principal Investigator, Dr. Shayne Piasta (614-688-4454; piasta.1@osu.edu). If you are injured as a result of participating in this study or for questions about a study-related injury, please contact Dr. Piasta. For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

To consent for your child to participate, please complete the next page of this form and the attached survey. Return all pages of this form and the survey to your child's teacher. Retain an additional copy for your records.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction.
I am not giving up my legal rights by signing this form. I will retain a copy of this form.
Please complete items (1), (2), (3), (4), and (5) below along with the attached survey.

ITEM (1) – Name of Child Printed name of child: _____

ITEM (2) – Research Participation (check one box and complete corresponding information)

☐ **YES** I voluntarily agree to permit my child to participate in this research and release his/her state data via state student identification number.

_____ _____
Printed name of person authorized to provide permission for child | Signature of person authorized to provide permission for child

_____ _____
Relationship to child | Date and time

☐ **NO** I do not want my child to participate in this research.

_____ _____
Printed name of person authorized to provide permission for child | Signature of person authorized to provide permission for child

_____ _____
Relationship to child | Date and time

ITEM (3) – Consent for Sharing of Lesson Observations for Educational Purposes

In addition to providing data for the research study, segments of Let's Know! lessons or classroom observation videos are sometimes used for educational purposes such as presentations, class lectures, and professional development of teachers. Do we have your permission to use video involving your child for these educational purposes?

☐ **YES** ☐ **NO** **Initial here:** _____

ITEM (4) – Consent for Release of Data to School/District

In addition to providing data for the research study, results from assessments may be shared with parents and/or the school/district. Do we have your permission to share data obtained from your child with their school/district?

☐ **YES** ☐ **NO** **Initial here:** _____

ITEM (5) – Authorization to Access Educational Records Related to Student Progress (FERPA Compliance)

I, the undersigned, authorize the school/district in which my child attends elementary school to release the following education records and/or any information contained therein: Third Grade English Language Arts state testing results.

_____ _____
Printed name of child | Date of Birth

I understand and acknowledge that: (1) I have made the choice to release my child's education records; and (2) that I have the ability to notify the project I choose to no longer participate in the study through The Ohio State University, but that any such revocation shall not affect disclosures made prior to the receipt of any such written revocation.

_____ _____
Signature of person authorized to provide permission for child | Date

Investigator/Research Staff – I have explained the research to the participant and his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy has been retained by the participant.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent | *Date and time*

Let's Know!2 – Opportunity for Supplemental Language and Comprehension Intervention

Researchers at MGH Institute of Health Professions, The Ohio State University, and University of Kansas/University of Kansas Medical Center have partnered with your child's school to study the *Let's Know!* intervention. This intervention provides supplemental early language and reading comprehension instruction to young children who may need extra support in these areas. We are studying children's language and literacy development from Grade 1 through the elementary years and whether *Let's Know*! better prepares children for later language and reading success. Several children in your child's school will be selected to experience the *Let's Know*! intervention and/or contribute data to this research study. This document provides information about the research study and seeks consent for you and your child to participate.

What You and Your Child Will Do

Participation in the research study is voluntary and open to children currently enrolled in Grade 1. Your child will continue to receive regular instruction as provided by their classroom teacher. If you consent to participate in the study, you will complete the attached survey (requiring approximately 15 min) and your child's teacher will also complete a brief survey. You may refuse to answer any survey questions without penalty. If you provide consent and your child qualifies:

- We will screen your child's language in the fall of Grade 1 with a small group of children or one-on-one. This will take about 10 minutes. Select children will be invited to participate in the study based on their need for extra support.
- If your child is selected to participate, we will assess your child's language and literacy skills in the fall and spring of Grade 1 and once in Grade 2 and in Grade 3. These assessments will be conducted at your child's school and will be administered by our highly trained research staff. Total assessment time at each time point is a maximum of 2.5 hrs, and will be conducted in multiple, short sessions. Participants will also receive four 15-minute progress monitoring assessments in Grade 1. Assessments may be audio recorded. With your permission, we will share assessment results with your child's teacher/school.
- Your child may be selected to receive *Let's Know*! lessons in a small group of 3-5 children. Lessons will occur four times a week for 25 weeks during Grade 1. These lessons will be provided by research staff in a quiet space at your child's school during the school day. Lessons will be videotaped so we can better understand how the program works. If your child is not chosen to receive these lessons, your child will continue to receive regular instruction in their classroom.
- We will obtain your child's annual school reading test scores plus state Third Grade English Language Arts scores. If you agree, we will obtain your child's scores from their school; you do not need to provide them.

If you consent for your child to participate in the research and your child is selected, you will receive a $25 incentive after your child completes assessments in Grade 2 and Grade 3. Your child will also receive small incentives (e.g., stickers) when they work with our staff.

Risks and Benefits

As reviewed and approved by the OSU Institutional Review Board, risks associated with participation in this research are not greater than those ordinarily encountered in daily life. Efforts will be made to keep your child's study-related information confidential. Children may participate in small groups, such that their peers will be aware of their participation and responses during sessions. Identifiable data will be stored on university (OSU, MGHIHP, KU/KUMC) servers and analyzed by investigators at these institutions. Because this is a federally funded study, non-identifiable research data may be used or shared with other researchers for research purposes only. Also, information may be disclosed if required by state law and may be reviewed by the following (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study.

You may refuse or discontinue participation in the research at any time without penalty or loss of benefits to which you are otherwise entitled. We may share a copy of this consent form with your child's school to show your willingness to participate and permission to work with your child.

Confidentiality
The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information and documents. The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations. Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions. You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Questions and Concerns
If you have questions or concerns about the research, you may contact the MGH IHP Project Coordinator, Dr. Maura Curran (617-643-0884; Mcurran1@mghihp.edu) or Principal Investigator, Dr. Tiffany Hogan (617-724-1054; thogan@mghihp.edu). If you are injured as a result of participating in this study or for questions about a study-related injury, please contact Dr. Hogan. For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the OSU Office of Responsible Research Practices at 1-800-678-6251.

To consent for your child to participate, please complete the next 2 pages of this form and the attached survey. Return all pages of this form and the survey to your child's teacher. Retain an additional copy for your records.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction.
I am not giving up my legal rights by signing this form. I will retain a copy of this form.
Please complete items (1), (2), (3), (4), and (5) below along with the attached survey and release authorization.

ITEM (1) – Name of Child Printed name of child: _____

ITEM (2) – Research Participation (check one box and complete corresponding information)

☐ **YES** I voluntarily agree to permit my child to participate in this research.

_____ _____
Printed name of person authorized to provide permission for child | Signature of person authorized to provide permission for child

_____ _____
Relationship to child | Date and time

☐ **NO** I do not want my child to participate in this research.

_____ _____
Printed name of person authorized to provide permission for child | Signature of person authorized to provide permission for child

_____ _____
Relationship to child | Date and time

ITEM (3) – Consent for Sharing of Lesson Observations for Educational Purposes

In addition to providing data for the research study, segments of Let's Know! lessons or classroom observation videos are sometimes used for educational purposes such as presentations, class lectures, and professional development of teachers. Do we have your permission to use video involving your child for these educational purposes?

☐ **YES** ☐ **NO** **Initial here:** _____

ITEM (4) – Consent for Release of Data to School/District

In addition to providing data for the research study, results from assessments may be shared with parents and/or the school/district. Do we have your permission to share data obtained from your child with their school/district?

☐ **YES** ☐ **NO** **Initial here:** _____

ITEM (5) – Authorization to Access Educational Records Related to Student Progress (FERPA Compliance)

I, the undersigned, authorize the school/district in which my child attends elementary school to release the following education records and/or any information contained therein: Third Grade English Language Arts state testing results; literacy progress measures administered by the school during Grades 1, 2, and 3.

_____ _____
Printed name of child | Date of Birth

I understand and acknowledge that: (1) I have made the choice to release my child's education records; and (2) that I have the ability to notify the project I choose to no longer participate in the study through The Ohio State University, but that any such revocation shall not affect disclosures made prior to the receipt of any such written revocation.

_____ _____
Signature of person authorized to provide permission for child | Date

Investigator/Research Staff – I have explained the research to the participant and his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy has been retained by the participant.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent | *Date and time*

Authorization to Release Student Information

Student's Name: _____

Grade Level: _____ Date of Birth: _____

School Name: _____

School Address: _____

Records requested for the following school years: _____

I hereby authorize _____ (school district's name) to release the student record information listed below for research study purposes. I understand that **only personnel who are working on the research project will have access to my child's student records**. Student information will not be given to others for any purposes, it will be de-identified, and no individual scores will be used in research reports. This information will allow the research personnel to better understand the cognitive and linguistic connections to academic progress.

I understand that student records include:

1. 3rd Grade MA State English Language Arts Test Scores
2. Teacher report of my child's classroom information in 1st Grade
3. School-administered literacy testing results for 1st, 2nd, and 3rd Grade

_____ _____

Signature of Parent or Guardian Date

Dear Educator,

We at the MGH Institute of Health Professions, The Ohio State University, and University of Kansas are conducting an evaluation of *Let's Know!*, a small-group, language-focused intervention for children. We are studying the effects of the Tier 2 intervention on the language and literacy skills of children at risk for language and comprehension difficulties. The study is funded by the National Institutes of Health.

You have been invited to complete this survey because you are an educator at a partner school involved in the project, and you work with one or more of children participating in our study. By completing this survey, you will help us understand the characteristics of students with whom you work and their Grade 1 experiences. We will ask questions about your teaching background, your school/classroom, and your instructional practices. We will also ask for your input about particular students to help us identify those eligible for study participation. Children's parents/guardians have provided permission for this information to be collected. The results of this research study will help us identify evidence-based best practices for supporting young children's language and comprehension development.

The survey should take no more than 20 minutes to complete. By completing and returning the survey, you are granting consent to participate in the research study and for us to use the information provided for research purposes. As reviewed and approved by the OSU Institutional Review Board, risks associated with participation in this study are not greater than those ordinarily encountered in daily life. Your participation is voluntary. Study-related information will be kept confidential unless disclosure is required by state law. Because this is a federally funded study, non-identifiable research data may be used by or shared with other researchers for research purposes only.

The National Institutes of Health has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information and documents. The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations. Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions. You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you have questions or concerns about the research, you may contact the MGH IHP Project Coordinator, Dr. Maura Curran (617-643-0884; Mcurran1@mghihp.edu) or Principal Investigator, Dr. Tiffany Hogan (617-724-1054; thogan@mghihp.edu). For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

Thank you for helping us in this important work!

Sincerely,

Dr. Maura Curran, Project Coordinator

Dr. Tiffany Hogan, Principal Investigator