

University of North Carolina at Chapel Hill

Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: June 4, 2018

IRB Study # 17-1299

Title of Study: An Examination of Response to Intervention in the Early Writing Skills of At-Risk Preschoolers

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Funding Source and/or Sponsor: DOE Institute of Education Sciences (IES)

What are some general things you and you child should know about research studies?

You are being asked to allow your child to take part in a research study. To join the study is voluntary.

You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study.

You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to learn about the Phonological Awareness + Letter Knowledge early literacy program for helping young children learn (pre)writing and other early literacy skills. In addition, we want to study what factors, such as attention and memory, might help or hinder the writing skills acquisition.

Are there any reasons your child should not be in this study?

Your child should not be in this study if she or he is not enrolled in a Head Start program, is not 3 years old at the time of enrollment, and does not have a good command of the English language.

How many people will take part in this study?

There will be approximately 299 people in this research study.

How long will your child’s part in this study last?

Your child will participate in this study for three years. Your child’s involvement in this study will include:

Year 1 a screening (5 minute writing task), a cognitive assessment (114 minutes), pre and post literacy assessment (each 75 minutes), and 14 small-group 16-minute sessions conducted in the Head Start classroom setting.

Year 2 a cognitive assessment (114 minutes), pre and post literacy assessment (each 75 minutes), and 14 small-group 16-minute sessions conducted in the Head Start classroom setting.

Year 3 Kindergarten a Literacy assessment (75 minutes)

What will happen if your child takes part in the study?

Following an initial screening, we will select children who may be at-risk for falling behind in writing, and we will randomly pick a second group that does not appear to be at-risk for falling behind. Both groups will receive an assessment of their literacy skills and selected cognitive abilities (i.e., fine-motor, language, problem solving).

We will ask you to complete behavior rating scales on your child, and we will ask the teachers to do the same. In addition, we will review your child’s school record to access demographic information.

For the group of children who are designated as at-risk, we will assign by chance one-half of them to an educational intervention designed to improve their writing skills. This group will include 99 children. During these sessions, your child will be asked to engage in specific tasks to improve writing and early literacy skills. If your child is designated as at-risk for this study, but not assigned to the educational intervention, he or she will continue to participate in the standard educational instruction in the classroom setting.

All procedures are a requirement for participation in the study.

None of these results will be shared with the school without your permission, and they will not be used for the purposes of promotion or the assessment of school progress, and they will not become part of the child’s school record without your permission.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to your child from being in this study may be that you can understand how your child’s (pre)writing skills develop and to provide targeted interventions for any specific needs that may be present.

What are the possible risks or discomforts involved from being in this study?

Your child may experience mild discomfort from being asked to do academic or cognitive tasks that may prove difficult or challenging. Our evaluators will be well trained to recognize these feelings of discomfort and they will provide positive encouragement to your child. Should your child refuse to answer a question, or even decline part or all of the testing, this request will be

respected. No other risks are suspected; however, there may be uncommon or previously unknown risks that might arise. We encourage you to report any problems to the researchers so that we may assist in addressing these problems.

What if we learn about new findings or information during the study?

You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will information about your child be protected?

All of the data collected in this project will be held in confidential, locked files dedicated to this project. Only project staff will have access to these files. Once your child is enrolled in the study, he/she will be assigned a specific ID number and all of his/her identifying information will be removed. There will be a single linkage file so that we can track your child over the four years of the study, or if we need to contact you, and that will be secured by the Principal Investigator and Project Coordinator in a separate locked file cabinet.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your child's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the Department of Education) for purposes such as quality control or safety.

What if you or your child wants to stop before your child's part in the study is complete?

You can withdraw your child from this study at any time without penalty. The investigators also have the right to stop your child's participation at any time. This could be because your child was unable to follow basic instructions or because the entire study has been stopped.

Will your child receive anything for being in this study?

Your child will receive small toys for his/her participation after each phase of the study. In the event that you, or your child, decide to stop participation, we would still like to give the small gift to your child.

You (guardian with signature rights) will receive several cash payments for taking part in this study. One \$50 payment will be given each study year. In the event that you or your child is unable or unwilling to participate in any aspect of the project, you will still will receive the gift cards.

Will it cost you anything for your child to be in this study?

It will not cost anything to be in this study.

Who is sponsoring this study?

This research is funded by United States Department of Education Institute for Educational Science. This means that the research team is being paid by the sponsor for doing the study. The

researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you or your child has questions about this study?

You and your child have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form.

What if there are questions about your child's rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

Printed Name of Research Participant (child)

Signature of Parent or Guardian with Signature Rights Date

Printed Name of Parent or Guardian with Signature Rights

Signature of Research Team Member Obtaining Permission Date

Printed Name of Research Team Member Obtaining Permission