**CHILD MIND INSTITUTE, INC.**
**INFORMED CONSENT FORM AND**
**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

**Print Participant Name: _____**

**Print Parent/Guardian Name: _____**

| | |
|---|---|
| **Sponsor / Study Title:** | **Child Mind Institute, Inc. / Neurocognitive Factors in EdTech Intervention Response** |
| **Principal Investigator: (Study Doctor)** | **Michael Milham, M.D., Ph.D.** |
| **Telephone:** | **646-625-4256 (24 Hours)** |
| **Address:** | **Child Mind Institute**<br>**101 East 56th Street**<br>**New York, NY 10022** |

You are being invited to allow your child to participate in a research study. This form contains information that will help you decide whether to allow your child to join the study.

## 1. Key Information

Things you should know:

- The purpose of the study is to determine the effectiveness of a new online (EdTech) reading intervention in relation to a new online math intervention.
- The National Institutes of Health (NIH) is sponsoring this research study.
- If your child participates, he/she/they will be asked to:
    1. Play a fun and interactive learning study game on a tablet provided by our study staff. This will be done at home for 20 minutes a day, 5 days a week, for 12 weeks. Total study gameplay time during the study is 20 hours.
    2. Complete a series of assessments of reading, language, math, and brain imaging at different points throughout the study. This will be done online and in person at the Child Mind Institute's Midtown or Harlem office.

Total assessment time during the study is between 14 and 16 hours which will take place over 5 study visits during the study.

3. As the parent or guardian, you will be asked to complete daily questionnaires given through a mobile phone app. The questions will be related to your child's study gameplay time as well as your level of involvement while your child is playing the study game.
4. Complete behavioral and psychological assessments including questionnaires and interviews. In these assessments, your child will fill out surveys about their behaviors (past and present) and complete an interview with one of our study team members.

- Risks or discomforts from this research are minimal and include tiredness and boredom during assessments and possible skin irritation from gel used during brain imaging.
- Your child may benefit from being in the study. Your child may see significant increases in their reading and math skills following treatment.

Taking part in this research is voluntary. Your child does not have to participate and can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study. The study doctor or study staff can explain words or information that you do not understand. If you decide to allow your child to take part in this study, you must sign your name at the end of this form and date it.

## 2. What is the purpose of this study?

The purpose of this study is to determine the effectiveness of a new online (EdTech) reading intervention in relation to a new online math intervention. These interventions are to be completed in the home. Although the main interest of this study is in evaluating the new reading intervention, we also want to determine whether the math intervention will improve reading skills and/or the reading intervention improve math skills. This is due to the overlap in important skills that may be common to both reading and math, including attention, working memory, and visuospatial skills. Given that many children with reading difficulties also have math difficulties, we expect that many children with reading difficulties will benefit from the non-overlapping parts of the math intervention as well. In addition to evaluating these interventions, this study will identify factors that are associated with outcomes (level of reading or math improvement).

This research is motivated by the need to make learning interventions more accessible by giving the intervention in the home. By providing the interventions as computer games, there is the potential for increased engagement and motivation to learn without

the need for a trained specialist. While the new reading intervention in this study has been supported by research, the studies are limited to school settings with a small number of participants. This study will enroll a large number of children who will complete the interventions in the home where you, as the parent or guardian, will be involved in your child's learning.

## 3. Who can participate in this study?

### 3.1 Who can take part in this study?

Your child is being asked to participate in this research study because your child has participated (or is currently participating) in the Healthy Brain Network research study, is between the ages of 6 and 11 years old, is a native speaker of English, and has tested in the below-average range on a measure of reading they completed as part of HBN.

### 3.2 How many people are expected to take part in this study?

Approximately 450 participants will participate in this study.

## 4. Information about Study Participation

### 4.1 What will happen during this study?

This study is a randomized-controlled trial. In this study, your child will be "randomized" into one of the two study groups: a reading-first intervention group or a math-first intervention group. "Randomized" means that your child has an equal chance of being assigned to both groups. This will be completed by an automated computer system after enrollment.

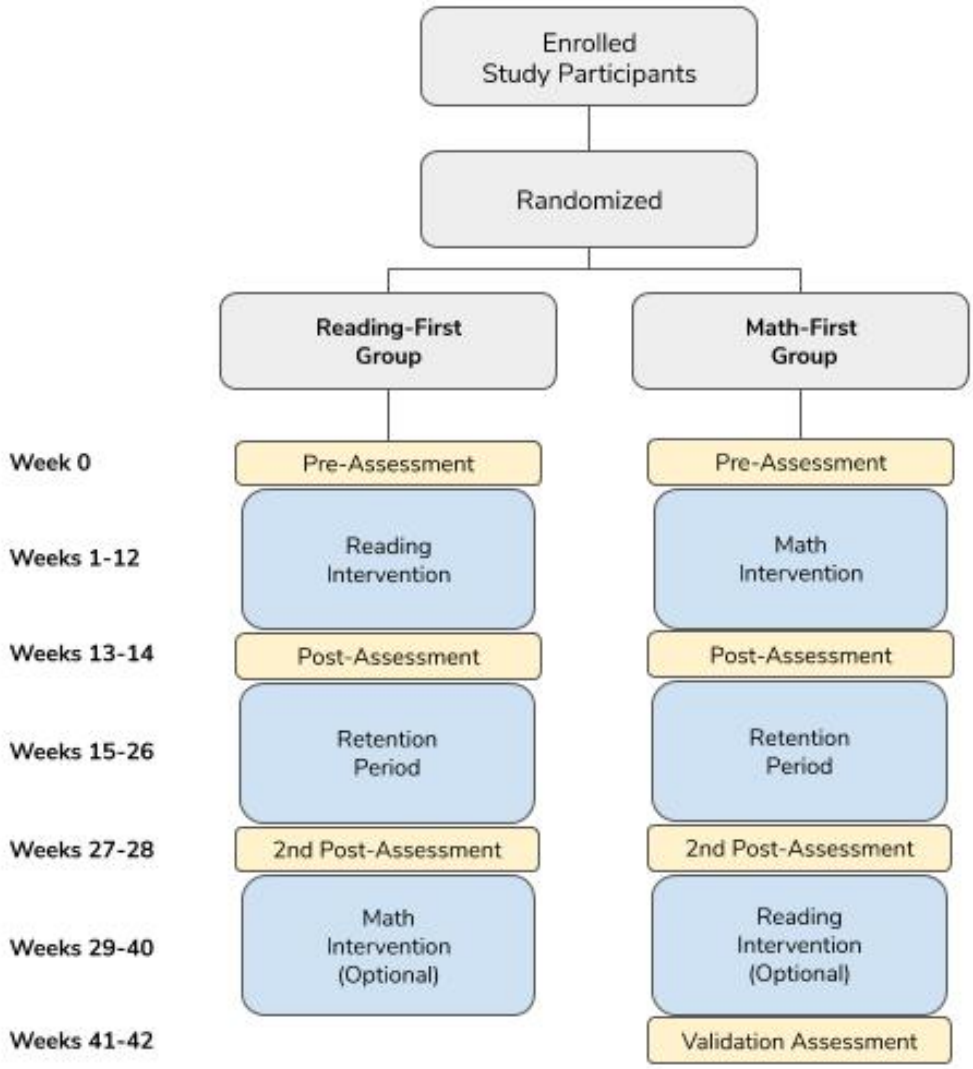
### 4.2 How much time will be needed to take part in this study?

- The entire duration of the study will last 28 weeks.
- Your child will complete 20 hours of study gameplay over a 12-week period.
- Your child will complete between 14 and 16 hours of assessments throughout the duration of the study.

Note if your child is assigned to the math-first intervention group, your child will have the option to complete the reading intervention at the end of the 28-week mark. Likewise, if your child is in the reading-first intervention group, they will have the option to participate in the math intervention at the end of the 28-week mark. Note that this will involve an additional assessment for the math first group.

The diagram on the following page shows more detail on the study design and timeline.

Diagram of study design and timeline:




### 4.3 What is the study treatment?

After enrolling in the study, your child will be randomized into one of the following groups:

- *Reading-First Group.* This group will play a computer-based game that trains children ages 6 and up on letter-sound association, decoding, and word reading.

- *Math-First Group.* This group will play a computer-based game that trains children ages 6 and up on numerical mathematical skills and cognition related to mathematical skills.

**How do the study games work?**

- Your child is given a tablet, provided by our study team, to take home. The study game your child has been assigned will already be uploaded onto the tablet. Before beginning the study game, you and your child will be introduced to the concepts and trained in the study game by study staff who are knowledgeable in the study game.
- Your child spends 20 minutes per day, 5 days a week, for 12 weeks playing the study game. Total study game play time is 20 hours.
- The study game will continuously log your child's performance for both accuracy and time and will adapt to your child's difficulty level. Your child will also get immediate feedback for each action in the study game.
- As the Parent or Legal Guardian, you are given access to an app that is downloaded onto your cell phone. This app will send you daily reminders to have your child complete the study game and to ask about your level of involvement.

**4.4 What are the assessments?**

For this study, we are collecting standardized measures of reading and reading-related skills, standard measures of math, and brain imaging. As the Parent or Legal Guardian, you will also complete a literacy questionnaire to learn about the effects of COVID-19 on literacy environment at home. The data from this study will be shared with other scientists around the world as a part of the Healthy Brain Network, as a way of encouraging more discoveries exploring brain development and markers for illness.

Below are the different types of assessments you and your child will complete should you take part in this study.

**Child Assessments:**

- *Standardized Measures of Reading and Reading-Related Skills*. Your child will complete assessments of reading, phonological processing, spelling, and vocabulary.
- *Standardized Measures of Mathematics.* Your child will complete assessments of essential mathematical concepts and skills.
- *Electroencephalogram (EEG) Measures*. Your child will complete reading-related tasks during brain imaging.

- Mental Health Assessment. Your child will fill out surveys about their behaviors (past and present) and complete an interview with one of our research staff.

**Parent or Legal Guardian Assessments:**
As a parent or legal guardian, your participation in this study is very important as well. During the evaluation, you will be asked to complete interviews and questionnaires that provide a wealth of information about your child's current and past psychological history, medical history, developmental history, and behaviors. We will also ask you about any medications your child may be taking. It is essential that the individual with the most knowledge about your child is present for all visits as this information will serve as the base for your feedback report.

In addition to answering questions about your child, we may also ask you about your health (physical and mental health) history. We may also ask about past and current substance use.

As the parent or legal guardian, you will complete a questionnaire related to your child's literacy in the home before COVID-19 and since COVID-19.

**4.5 When and where do the assessments take place?**
Your child will complete assessments both in-person and remotely. In-person assessments will be completed at Child Mind Institute's Midtown location or at our Harlem Office. There will be four assessment time points throughout the study: Before, during, and after the intervention, and a 2nd round of assessments after a retention period. The total duration for the completion of assessments ranges from 14 to 16 hours across the entire length of the study.

- *Pre-Intervention Assessments (Week 0).* All participants will complete assessments in reading and math, along with EEG measures. The total time for these assessments is approximately 4 hours (2 hours of remote assessments; 2 hours of in-person assessments).
- *Mid-Intervention Assessments (Week 6).* Participants assigned to the reading-first intervention group will complete a reading assessment. The total time for this assessment is 10 minutes. This assessment will be administered remotely.
- *Post-Intervention Assessments (Week 13).* All participants will complete assessments in reading and math, along with EEG measures. The total time for these assessments is approximately 4 hours (2 hours of remote assessments; 2 hours of in-person assessments).
- *2nd Post-Intervention Assessments (Week 27).* All participants will complete assessments in reading and math, along with EEG measures. The total time for

these assessments is approximately 4 hours (2 hours of remote assessments; 2 hours of in-person assessments).

If your child is assigned to the math-first intervention group and your child would like to complete the reading intervention, there will be an additional round of assessments.

- *Validation Assessments (Week 42).* Participants assigned to the math-first intervention group who decide to complete the reading intervention will complete assessments in reading and math, along with EEG measures. The total time for these assessments is approximately 4 hours (2 hours of remote assessments; 2 hours of in-person assessments).

**4.6 What are the expectations if I decide to allow my child to take part in this study?**
Your child will be expected to complete all remote assessments prior to in-person visits. As the Parent or legal guardian, you are expected to complete daily check-ins using the cell phone app to monitor your child and your involvement.

**4.7 If I decide not to take part in this study, what other options does my child have?**
This research study is for research purposes only. The only alternative is to not participate in this study.

## 5. Information about Study Risks and Benefits

**5.1 Potential Risks or Discomforts**
Risks associated with all tasks are minimal, however, your child may become frustrated, bored or fatigued during test sessions or participation in the intervention. Participants may become bored or fatigued during behavioral assessment as well. Skin irritation is rare but could occur during an EEG from the electrodes or gel that is used.

You will have video and audio recordings taken for this study. It is possible that your face or voice may be recognizable, and your identity may be known.

The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

There may be other study risks that are still unknown.

**5.2 New Findings**
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

### 5.3 Benefits

If you and your child chose to participate, your child may see increases in their reading and/or math skills following study treatment. All participants will be provided with the results of standardized behavioral assessment battery. Additional benefits that may develop from the research are likely to be realized by society at large and may include better understanding of the possible effectiveness of this study treatment and the possible behavioral and neurobiological predictors of study treatment response.

## 6. Compensation for Participation

Participants will be reimbursed at a rate of $50 per imaging session. All participants will be expected to attend three sessions (baseline, immediate post-intervention assessment, retention assessment); participants assigned to the math-first intervention group will be asked to attend an additional assessment after being given the reading intervention. Participants will also be reimbursed $25 for transportation to each session. Participants will not be reimbursed for remote visits and regular check-ins.

## 7. Confidentiality

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) 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. If the results of this study are published or presented at meetings, you will not be identified.

We will take measures to protect your and your child's privacy and the security of all your child's personal information. Following your child's enrollment in the study your child will receive a study identification number or code that will be used on all information and data collected for the study. Information and data will be collected on paper or using secure electronic systems. Your child's name and other identifying information will be maintained in locked files and/or restricted password-protected databases and secure servers. In all cases, your child's information and collected data will be available only to authorized members of the research team.

Data collected electronically for this study will be entered into our electronic medical record system, called NextGen, and stored via secure servers. NextGen will provide us with the software to complete the questionnaires on the computer. This system also ensures the privacy of participant records by defining strict user access levels. Imaging

data, including EEG data, will be collected via secure computers and stored remotely via a system designed with security and restricted/controlled access features.

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

**8. Audio and Video Recording**

As a part of the research study, we would like to both videotape and/or audiotape your child completing certain tasks. The recordings will be used for analysis by the research team for scoring of assessments.

Audio and/or video recordings will not be labeled with any identifying personal information. Video recordings may contain facial features or facial pictures but will also not be labeled with any identifying data. These recordings will be stored digitally on secure servers as outlined previously. Recordings will not be labeled with identifying personal information. These recordings will be kept with the rest of the research data indefinitely.

Your initials below grant the study doctor to record your child as described above during participation. The study doctor will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission. Recording is required in order to score assessments.

YES, you may record my child and me during participation.
Parent/Guardian Initials _____

NO, you may not record my child and me during participation.
Parent/Guardian Initials _____

**9. Costs**

There will be no cost to you for participation in this study. The study-related procedures, and study visits will be provided at no charge to you or your insurance company.

**10. Whom to contact about this study**

During the study, if your child experiences any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care for your child, or hospitalization is required, alert the treating physician that you are participating in this research study.

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

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00046460.

**11. Voluntary Participation/Withdrawal**

Your decision to participate in this study 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 and without any effect on your future medical care. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your child's participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to your child;
- If you or your child fail to follow directions for participating in the study;
- If it is discovered that your child does not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

**12. 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 my child participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant's Printed Name

_____

Parent or Legal Guardian Name

_____ _____

Parent or Legal Guardian Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to have your child participate in this study, the study doctor and research team will use and share health data about you to conduct the study.

Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.
- Information obtained from all your Healthy Brain Network study visits.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of the Child Mind Institute.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this research, if applicable.
- A data safety monitoring board which oversees this research, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the computerized study interventions works.
- To compare the effects of the computerized study interventions.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

**STATEMENT OF AUTHORIZATION**

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Participant's Printed Name

_____

Parent or Legal Guardian Name

_____ _____

Parent or Legal Guardian Signature Date