HENRY FORD HEALTH	Participant Name: MRN: Date:

APPROVED
September 24, 2025
INSTITUTIONAL REVIEW BOARD

PROJECT TITLE: Evaluation of a Technology-Based Parenting Intervention for Young Children (PYCC) Behavioral Health Challenges Identified in Pediatric Primary Care

Protocol Version # and Date: 1 and 9.15.2025

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Principal Investigator (PI): Dr. Tisa Johnson (Henry Ford) and Dr. Lucy McGoron (Wayne State University)
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PI Phone: 313-664-2500 (Dr. McGoron)
Sponsor: Blue Cross, Blue Shield Foundation

1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when deciding whether to participate. More detailed information is provided in the body of the consent. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
Voluntary Consent. You are being asked to participate in a research study because you are the parent of a child ages 2-5 years old and reported some challenging child behavior on a screener. Participation is voluntary. There will be no penalty or loss of benefits if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is examine the impact of **Duration**. It is expected that your participation will last three months. You will spend about 20 minutes participating today while you are receiving pediatric care, 20 minutes participating in one month (on your own time at home), and 20 minutes participating three months from today (on your own time at home). **Procedures and Activities**. You will be asked to answer some questions about yourself and your child. Then you will be put in a group where you learn about the Parenting Young Children Check-up (PYCC) program and are then free to use the program as much or as little as you'd like, or you will learn about the program in three months. We will also ask you to complete online questionnaires, online in your own time at home, one month from today and three months from today.

Risks. Some of the foreseeable risks or discomforts of your participation may include feeling uncomfortable answering some of the questions. More detailed information can be found in the "*What are the Risks, Discomforts, and Inconveniences of Participating in the Study?*" section in the Consent Form.

Benefits. Some of the benefits that may be expected include learning parenting strategies to promote your child's best behavior.

Alternatives. Participation is voluntary, and the only alternative is to not take part in this research study.

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

This project is funded by the Blue Cross, Blue Shield Foundation. The Henry Ford Health (HFH) investigator on this study is also healthcare providers. She is interested in the knowledge to be gained from this study and are interested in your well-being. Investigators may obtain salary or other financial support for conducting the research.

3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you are the parent of a young child (ages 2-5 years old) and reported some challenging behavior on the Preschool Pediatrics Symptoms Checklist screener and expressed openness to participating.

A total of 40 people will be enrolled at HFH.

The purpose of this research study is to examine the impact of an online program called the Parenting Young Children Check-up (PYCC). This is a pilotclinical trial of this program. Past research shows parents positively rate this program and find it helpful. We want to learn if the program is impacts parenting, parenting stress, and child behavior. We will do this by having some parents (20 in total) use the program now and some parents (20 in total) use the program in a few months.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this study, your participation will include completing online questionnaires today and at two additional time points (on your own, at home; you will get a phone call prompting you to complete them) over the next three months.

There will be two groups in the study. You will be randomized into one of the study groups described below. Randomization means that the group you are assigned to will be chosen by chance, similar to flipping a coin. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in group 1 (often called "Arm A" or the 'treatment group'), you will learn about the PYCC program today, receive text messages from the program, and be free to use the online program as much, or as little, as you choose over the next three months.

If you are in group 2 (often called "Arm B" or the 'control group'), you will not learn about the PYCC today, but will learn about it in three months, and be free to use it as much, or as little, as you like then.

At study visit 1 (done today, at your child's doctor's appointment through RedCap), the following procedures will be performed:
• Completing questionnaires ; being placed in one of two groups
At study visit 2 (done in one month, online in your home through RedCap), the following procedures will be performed:
• Completing questionnaires
At study visit 3 (done in 3 months, online in your home through RedCao), the following procedures will be performed:
• Completing questionnaires

For some research studies, such as the one you are being asked to join, it is important that you do not learn the results of certain tests. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study.

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF PARTICIPATING IN THE STUDY?

While you are in the study, you are at risk for the following side effects:

- Emotional risks (e.g., feelings of sadness or anxiety): You may feel uncomfortable answering some of the questions about you or your child.

Likely
• You may feel uncomfortable answer some of the questions
Less Likely
• None known
Rare
• It may become known that you participated in this research
Rare and potentially Serious
• None know

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected*?"

The researchers will try to minimize these risks by allowing you skip questions you would rather not answer and how much/little you use the PYCC (either now, if you are in intervention group, or in the future, if you are in waitlist control group) is completely up to you.

There may be additional risks or discomforts that are not known at this time.

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research team member you are meeting with.

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include gaining information about parenting to promote your child's best behavior. However, there is also a chance you may not directly benefit from this research, but what we learn may help others in the future.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

Participation is voluntary. The only alternative is to not take part in this research study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research information may not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers. Identifying information will be maintained in online, password-protected for two years and then deleted. De-identified (i.e., without your name or other identifying information) collected data will be kept indefinitely. This data will be stored on the website for the Open Science Foundation (OSF; see more below).

You should also know that the HFH Institutional Review Board (IRB), the HFH IRB Administration Office, Wayne State University IRB may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Future Research

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without your additional informed consent. De-identified data filles (containing no names of participants) will be stored in a data repository through OSF (Open Science Foundation) indefinitely. Storage, and protection, of

these data files with be overseen by Drs. Johnson and McGoron. As a participant, you have the right to withdrawal data included in the datafile at any time.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. WHO DO I CONTACT WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Drs. Johnson and McGoron, pediatrician (Henry Ford Health) and Assistant Professor (Wayne State), or their staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Dr. McGoron by phone at 313-664-2500 or by email at Lucy.K.McGoron@wayne.edu. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, report problems or concerns, ask questions, obtain additional information, or offer input with an informed individual who is unaffiliated with the research study, you may contact the Henry Ford Health IRB Administration Office by phone at (313) 874-4464 or by email at IRBQuestions@hfhs.org.

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.

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

You do not have to answer any questions that you do not want to answer.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

13. WILL IT COST ANYTHING TO PARTICIPATE?

There will be no charge to you for your participation in this study. The PYCC program will be provided at no charge. You will still be responsible for the cost of your usual ongoing medical care, including the pediatric care your child receives. You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff.

The sponsor and/or Henry Ford Health will pay for the tests and examinations that are required by this study and anything else that is not part of your standard medical care. While some of the tests and exams may be considered standard of care, they may or may not be covered by your medical

insurance. You may be responsible for insurance co-payments. If your medical insurance does not pay for your care, you may be responsible for the cost of the medical care related to your condition including but not limited to laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization, and procedures.

14. WILL I BE PAID TO PARTICIPATE?

For taking part in this research study, you will be paid for your time and inconvenience. You will be paid $30 today and then, if you complete study questionnaires one and three months later, you will receive an additional $30 each time. You will be paid after completing each set of questionnaires. If you complete the study, you will be paid a total of $90. If you do not finish the study, you will be paid for the part that you did complete.

Study Visit	Amount
Visit 1 (completed today, online at your doctor's visit)	$30
Visit 2 (completed online in your home)	$30
Visit 3 (completed online in your home)	$30
Total (if you complete all visits)	$90

You will receive payment via a Tango Cards (issued by Wayne State University), which is an online system that allows you to select gift cards in the amount your received for each part of this study. Each time you receive a payment for participation in this study, you will receive an email about the amount of money available. Tango Cards is administered by an outside company. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. In order to receive payment, we will need to collect some information about you, including your name and email address. All information is stored in a secure fashion.

Research using your data can lead to new discoveries, such as new tests, drugs, or devices. Your data may be used for commercial profit, however, you will not have rights to these discoveries or any proceeds from them.

DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I am willing to be contacted for participation in future research studies. Please initial below.

_____ I agree

_____ I refuse

My de-identified data may be stored and used for future research. Please initial below.

_____ I agree

_____ I refuse

_____ _____ _____
Signature of Participant Date Time

_____
Printed Name of Participant

_____ _____ _____
Signature of Witness to Consent Date Time

_____
Printed Name of Witness

_____ _____ _____
Signature of Person Obtaining Consent Date Time

_____
Print name of Person Obtaining Consent

I

INFORMATION ABOUT CONFIDENTIALITY AND HIPAA AUTHORIZATION

A federal regulation, known as the Health Insurance Portability and Accountability Act (HIPAA) gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any PHI collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The Principal Investigators (PI) and their research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and their research team to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

We will collect and use:

- Demographic information
- Results of the Preschool Pediatric Symptoms Checklist (PPSC)

This health information may contain your name, address, phone number, email address, date of birth, medical record number, social security number, unique characteristics or code, etc.

We may release this information to the following people:

- The Principal Investigators and their associates who work on or oversee the research activities.
- Henry Ford Health Institutional Review Board(IRB)
- Wayne State University Institutional Review Board (IRB)

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by federal privacy (i.e., HIPAA) regulations.

This Authorization, any test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at the research study information that is not in your medical record.

No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This Authorization to use and release your personal protected health information does not expire.

You do not have to sign this Authorization and may cancel it at any time. If you decide to cancel your Authorization at later date, you will not be able to continue to participate in this study. If you withdraw your permissions, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the following:

Dr. Lucy McGoron
71 E. Ferry St.
Detroit, Michigan 48202

By signing this document, you are authorizing the PI to use and disclose PHI collected about you for the research purposes as described above.

_____	_____	_____
Signature of Participant	Date	Time

_____
Printed Name of Participant