



Research Subject Informed Consent Form

Title of Study:	When to Wonder s18-01057
Principal Investigator:	Helen Link Egger, MD Department of Child and Adolescent Psychiatry NYU School of Medicine 1 Park Avenue, 7 th Floor 646-754-5050
Emergency Contact:	Helen Egger 646-754-5279

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must digitally sign this form. We will email you a copy of this form signed by you for you to keep.

Some of the people who may be able to take part in this study may not be able to give consent because they are under 18 years of age. As their parent you will be asked to give consent.

2. What is the purpose of this study?

When to Wonder is a smartphone-based application for parents and their children. The purpose of this research study is to use the *When to Wonder* smartphone app as an mHealth (mobile health) tool to build a population-level understanding of children’s emotions and behaviors as they develop and grow. We want to better understand children’s emotions and behaviors, the role parent-child interaction plays in child development, and how different individual, family, and community experiences impact children’s emotions and behaviors. The app will also give parents science-based information that may help them better understand their child’s emotions, behavior, and development.

This research study is being done through collection of your and your child’s thoughts, reactions, and opinions using this mobile application. We will collect this information through Questionnaires, Audio and Video Recordings, and Interactive Games.

Parents and children enroll in this study together. You qualify for this study because you are at least 18 years old and the parent or legal guardian of a child. Your child qualifies for this study if he or she is 6 years old or younger.

3. How long will I be in the study? How many other people will be in the study?

This study will last for as long as you keep using the *When to Wonder* app. It is up to you to decide how often you and your child use the app. There is no limit to the number of times you can use the app.

Around 10,000 parent-child pairs will be in this study.

4. What will I be asked to do in the study?

First you will be asked to give consent. If you choose to take part in the study, we will ask you to digitally sign this consent form before you continue using the *When to Wonder* app.

After consenting to participate on the app, you will complete a registration process on the app. Registration includes entering your email address and verifying your email address. After you verify your email address, we will email you a signed copy of this consent form.

After registration, you will be asked questions about your and your child's names, genders, month/year of birth, zip code, your family structure and your child's health. You will be asked detailed questions about your child's emotions, behaviors, and development related to topics such as picky eating, temper tantrums, anxiety, and sleep.

You will be asked to play a game where you report on the foods your child will or won't eat (Yummy/Yucky Game).

Your child will be asked to play the same Yummy/Yucky Game where he/she reports on the foods he/she likes or doesn't like. Your smartphone's microphone will audio record what your child says while playing the game. We will use statistical methods to analyze these audio recordings to explore how your child's verbal reactions to the food game are related to his/her emotions, behaviors, and development.

Your child will be asked to watch a few short (15 – 30 seconds) video clips. Your smartphone's front-facing camera will record short videos of your child watching the clips. In two of the video activities, the phone is like a mirror and the child will share his or her yummy or yucky face. We will then use new technology that automatically identifies emotions and behaviors from the videos of your child so that we can explore how your child's emotional responses (i.e., positive, negative, neutral reactions) to the videos and behaviors are related to his/her emotions, behaviors, and development.

As you and your child complete activities on the *When to Wonder* app, you will be offered science-based information about your child's emotions, behaviors, and development. You will be offered suggestions about how to engage your child in science-based, developmentally appropriate, participatory learning activities. These are activities you and your child can do together in your daily life, away from the phone.

In the future, we may add new activities to the *When to Wonder* app, such as new games, new video clips to watch, new questionnaires, and new requests for audio and/or video recordings of you, your child, and your environment. You will be told about these new activities and asked if you want participate.

You can choose when you want to do the Questionnaires, Audio and Video Recordings, and Games in the *When to Wonder* app. Activities do not need to be completed in a single session or in a specific order. There is no timeline for completing the activities within the *When to Wonder* app. You can use the app wherever it is safe to access your smartphone.

The *When to Wonder* app will collect information about how you use it. This way, the study investigators can find out more about how many participants drop out of the study, how often the app is typically used by participants, how long it takes to complete the survey questionnaires, which specific activities of the app are used, and generally how you interact with the app.

You are free to skip any questions that you prefer not to answer or activities that you prefer not to participate in.

Time Commitment

Giving electronic consent and registering for the study on a smartphone should take 5 – 10 minutes. The amount of time you spend answering questions, playing games, and recording videos today and in the future is up to you. The time it takes to complete different activities ranges from about 15 seconds to watch a video clip up to about 10 minutes to complete a survey.

Study Audio/Video Recordings

Audio and video recordings are required for participation in this study. If you do not wish to be recorded, you cannot participate in this study.

This study will include audio and video recordings. We will collect audio recordings during the child Yummy/Yucky Game. We may ask you to record an audio recording about your child and your concerns. Your child will be asked to watch a few short (15 – 30 seconds) video clips. Your smartphone's front-facing camera will record short videos of your child watching the clips. In two of the video activities, the phone is like a mirror and the child will share his or her yummy or yucky faces.

The video and audio recorded will be stored temporarily on your phone until it is automatically uploaded to our NYU Langone data storage servers. You are not able to review or delete the recordings.

If you give us permission to share your research data with other investigators, this could include your audio/video recordings.

Data Storage and Protection

Data will be maintained on NYU Langone servers and accessible from the NYU Langone network meeting current requirements for storage of potentially identifiable data. Private information will be stored indefinitely within NYU Langone data center infrastructure only accessible on an internal network to developers and researchers through a secure network connection. Your name, your child's name, and your email address will be stored separately from the study data and a unique ID will link the two files. Researchers will not have access to names and email addresses.

5. What are the possible risks or discomforts?

There are possible risks, discomforts, and inconveniences associated with any research study. You may experience frustration that is often experienced when completing surveys. You might feel uncomfortable answering questions about yourself or your child. You may feel inconvenienced by having to enter information into the app or by seeing the reminders or messages that are sent by the app. Some questions may be of a sensitive nature, and you may therefore become upset as a result. However, such risks are not viewed as being in excess of “minimal risk”.

This study does not involve testing any new drugs or therapies so we do not expect any medical side effects from participating. There is no anticipated medical risk involved with completing Questionnaires, Audio and Video Recordings, and Games. The app is not designed to give medical advice or to make suggestions related to treatment or medications. If you have any medical concerns, seek medical care.

There are other risks such as maintenance of privacy and breach of confidentiality. For example, someone who sees the app on your phone may conclude that you are wondering about your child’s emotions, behaviors, and development.

Any information you provide is completely up to you. If you feel uncomfortable at any time, stop the task. You can withdraw from the study at any time.

As with any smartphone app, use common sense and follow laws about when and where you use your smartphone. Just as you would not text while driving, do not interact with the app while driving or doing other activities that could result in injury. Wait until you are in a safe place to perform any app-related tasks.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

Participating in this app-based study may or may not provide any direct benefit to you or to your child. The potential direct benefit you are expected to get from being in this research study is the perceived value of information about children’s emotions, behaviors, and development; suggestions about how to engage your child in science-based, developmentally appropriate, participatory learning activities; and feedback about how your child’s emotions, behaviors, and development compares to other similarly aged children.

This study has anticipated benefits to society because the information you provide will expand our population-level understanding of children’s emotions, behaviors, and development.

8. What other choices do I have if I do not participate?

You may choose to not participate in this research study.

9. Will I be paid for being in this study?

You will not be paid for participating in this research study.

10. Will I have to pay for anything?

You will not have to pay anything for participating in this study. Being in this research study will not lead to extra costs to you, other than usage of your mobile phone data plan, if applicable. Data collected in this study will count against your existing mobile data plan, but you can set up the app to use only Wi-Fi connections to limit the impact on your data plan. We will provide you with instructions on how to do it.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all study activities and all information has been collected. This study may also be stopped or your participation ended at any time by the study without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

14. HIPAA Authorization.

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section.

Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Other study sites involved in the research

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study or use the *When to Wonder* app.

Can I change my mind and withdraw permission to use or share my information?

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form or through the "Contact Us" button in the app. Simple deletion of the *When to Wonder* app is not the same as withdrawing from the study. If you withdraw your permission, you will not be able to stay in this study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used. If you decide that your previously collected information cannot be used every effort will be made to delete previously collected information. However, we cannot guarantee that all information collected by *When to Wonder* will be permanently deleted.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it. Simple deletion of the *When to Wonder* app is not the same as withdrawing from the study. To withdraw from the study you must follow the steps outlined above.

15. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

NYULMC would also like permission to contact you in the future with information about additional studies for which you and your family may be eligible.

To give these additional permissions, check the boxes below and write your initials where indicated. You may still participate in this study even if you do not give us these additional permissions.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional policies. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back these additional permissions at any time.

- Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

Subject Initials

- Checking this box indicates my permission to contact me with information about future research studies.

Subject Initials

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing for you and your child to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)

Signature of Subject

Date