The Children's Hospital of Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title: Evaluating an eHealth solution for screening in pediatric care

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You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to you as the parent and "your child" refers to your child.

Study Overview

You and your child are being asked to take part in this research study because your child has recently experienced an illness or injury that caused them to come to the hospital or see their doctor at the office or clinic. This study is being completed at CHOP and the University of Kentucky.

The purpose of this research study is to learn about how an online screening tool may be useful to children and parents in helping children recover well after an injury or illness, or manage ongoing symptoms.

The online tool includes a game (like a video game) for young people to play on a tablet, in which they also answer a few questions to rate how they are feeling, and brief weekly updates (text or email) for parents.

If you and your child agree to take part, your participation will last for about 30-60 minutes at the initial visit. Your overall participation will last for about 12 weeks and will involve 2 follow-up phone calls in about 6 and 12 weeks that could take about 30 minutes each. Some children and parents will also spend a little time playing an online game (child) and receiving weekly messages (parents). Children in either group will have the option to play the game after their study participation ends, if they choose.

There is very little risk from this study. You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Please see below for additional details about the study.

What are the study procedures?

Randomization

You and your child will be assigned to one of two groups, either an intervention or a usual care group. The group you are in will be assigned by chance, like flipping a coin. For this study, there is a 2-to-1 chance of being in the intervention group: 2/3 families will be in the intervention group and 1/3 will be in the usual care group.

In the usual care group

- Your child will get all the usual care from the doctors and health care team
- After completing the 12 week follow-up questionnaires, we will invite your child to play the online game if they want to.

In the intervention group:

- Your child will get all the usual care from the doctors and health care team
- Your child will play the online game at least 3 times a week for the next 6 weeks – inside the game they will answer a few questions about how they are feeling
- You will receive brief weekly updates (text or email messages) on how your child is rating how they are feeling. Each message will have a link to more information.

Interviews and questionnaires:

- We will ask for some basic information about you and your child, such as age and ethnic background, and you and your child will complete questionnaires about pain, symptoms, and feelings and thoughts.
- In about 6 and 12 weeks we will ask you to complete some more questionnaires over the phone or online.

Using the game and messages (Intervention group only):

- We will provide your child with their password and show them how to log in.
- Your child will log in online at home at least 3 times per week for 6 weeks, so that they can enjoy the game and rate how they are feeling. We will ask you to help remind them.
- We will send you brief weekly updates via text or email.

Using the game (Usual care group only):

- After the 12 week questionnaires, we will provide your child with their password so that they can log in to play the game if they want to. If they play the game, we will ask them their opinion about it.

Visit schedule

Visit	Main Procedures	Duration
Time 1	Questionnaires *Intervention group: Get log-in information + start to play the game*	30-60 minutes
Over the next 6 weeks	*Intervention group:* *Child - Log in on their tablet at least 3 times / week to use the game & rate how they are feeling* *Parent – Read brief weekly updates about child ratings and click through to learn more*	*15 minutes or more per week* *(depends on how often your child uses the game)*
Time 2: 6 weeks	Follow-up questionnaires	30 minutes
Time 3: 12 weeks	Follow-up questionnaires	30 minutes
After 12 weeks	*Usual care group:* *Child - Log in on their tablet to use the game if they want to, answer a few questions about how they like it*	*(depends on how often your child uses the game)*

The team will review medical records and collect other information:

- We will collect information from your child's medical chart about their diagnosis, treatment, and reason for coming to the hospital or clinic / doctors' office.
- Whenever your child uses the game, we will keep track of the time and date, how long they use it, their responses to questions within the game, and which activities they complete.
- When you receive a message, we will keep track of whether you open it and whether you click on any links that are provided.

What will be done with my data during the study?

Your data will be stored at CHOP, and at an outside vendor, Radiant Creative LLC, the company that is helping our team to build these online screening tools. Your data will be labeled with a study ID number, rather than your name. During the study, we will store your name and contact information separately so that we can reach you. The outside vendor will not know who you are.

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you. We will not

share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

Risks of completing interviews and questionnaires

There is very little risk in answering questions about symptoms or pain related to injury or illness and about how you or your child are thinking and feeling. It could be briefly upsetting for some caregivers and children. If you wish, the person you talk to for this study can tell you where to get help, should you become upset. In addition, you do not have to answer any questions that make you feel uncomfortable.

Risks of using the game and parent messages

There are no known risks of using the game or parent messages.

Risks of collecting your data

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality. Each participant will be assigned a study ID number. This number will be used on data collection forms and in the database instead of names and other private information. During the study, a separate list will be maintained that will link your name to the study ID number so that we can communicate with you. When the study is complete, we will destroy the list that links your name to the study ID number.

Are there any benefits to taking part in this study?

You and your child will not benefit directly from taking part in this study.

You and your child may feel better after answering questions about how they are feeling. If you are in the intervention group, your child may enjoy playing the game and may find it helpful to rate how they are feeling. You may find it helpful to get the weekly updates.

The knowledge gained from this research may help doctors promote child physical and emotional recovery, and help us to make our online screening tool more useful, benefitting families in the future.

Do you need to give your consent in order to participate?

If you and your child decide to participate in this study, you must sign this form. We will ask your child for their assent as well. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You and your child do not have to take part in order to receive care at CHOP.

If you and your child decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You and your child can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and/or your child will be collected. This will include information from medical records, interviews and questionnaires. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP and the University of Kentucky;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The National Institutes of Health who is sponsoring this research;
- You and your child's data will be shared with an outside vendor, Radiant Creative LLC, the company that is helping our team to build these online screening tools. Your data will be labeled with a study ID. The outside vendor will not know who you are. Private information such as your name or medical record number will not be shared with them. They may gather your IP address automatically when your child plays the online game or you click to look at information from the weekly updates. They will not share this data with anyone outside the study team.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue

until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Where will study data and results be shared?

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

As part of the study we will collect information that may be useful for research in the future about childhood illness and injury. Therefore, you and/or your child's data (with all identifiable personal information removed) will be stored in a data archive to be used in future analyses. In the data archive, your data will be stored with a code number that cannot be linked back to you. If you leave the study, we will not be able to re-identify which data are yours. Your data will remain part of the research.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for other scientific research**.**

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute of Child Health and Human Development (NICHD) may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Nancy Kassam-Adams
The Children's Hospital of Philadelphia
Roberts Center for Pediatric Research

2716 South Street, 13th floor
Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you and/or your child are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you and/or your child by taking part in this study.

Will you and/or your child be paid for taking part in this study?

- Parents who are in the study will receive a thankyou gift for each research assessment: $10 for Time 1, $20 for Time 2, and $20 for Time 3.
- Children who are in the study will receive a thankyou gift for each research assessment: $10 for Time 1, $20 for Time 2, and $20 for Time 3.
- For the Intervention group only, parents can receive an additional thankyou gift of up to $30 depending on their own and their child's use of the system over the initial 6 weeks.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Nancy Kassam-Adams at (215) 590-3118. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

Your data will be stored with a code number that cannot be linked back to you. If you leave the study, we will not be able to re-identify which data are yours. Your data will remain part of the research.

Optional: Contact in the Future

We may wish to contact you and/or your child again at a later date to invite you to participate as future "testers" in later stages of testing this online screening tool. Please

indicate below with your initials whether or not we may contact you in the future if we have additional questions or updates about this web-based resource for children.

_____ (initials) You may contact me at a later time.

_____ (initials) I do not wish to be contacted again at a later time.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to you and your child's participation. You are also agreeing to let CHOP use and share your child's health information as explained above. If you don't agree to the collection, use and sharing of your child's health information, your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Consent for Parents' participation

Name of Parent or Guardian Participating	
Signature of Parent or Guardian Participating	Date

Relation to child subject: ☐ Parent ☐ Legal Guardian

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date