Protocol Title: Virtual Reality-based Rehabilitation for Children with Traumatic Brain Injuries

Principal Investigator: Susan Quinn, MD

Site Principal Investigator: Stacy Suskauer, MD

Description of Subject Population: 6-17 years old, all genders, all races, all ethnicity groups

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to give permission for your child to take part. If you decide to give permission for your child to take part now, you can change your mind and s/he can drop out later. Your decision won't change the medical care your child gets within Kennedy Krieger Institute now or in the future. The following key information is to help you decide whether to give permission for your child to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

The goal of this study is to learn more about whether playing certain virtual reality video games could help children with traumatic brain injuries regain some cognitive skills.

How long will your child take part in this research study?

Your child may join this study while a patient at Kennedy Krieger Institute or by coming to the Kennedy Krieger Institute for study visits. If your child is an inpatient at Kennedy Krieger Institute your child's duration of participation will continue during their stay at the hospital and then we will have one visit a month after discharge. If your child joins the study as an outpatient participation will include at least 3 visits over approximately 1-2 months.

What will happen if your child take part in this research study?

If you decide to give permission for your child to join this research study, the following things will happen: there are three assessment visits for your child - the baseline visit, the post-intervention visit, and the 1-month follow-up visit. Each visit is about 60 minutes and includes paper-based and computerized tests and questionnaires. Between the baseline and post-intervention visit, your child will be playing our virtual reality games for at least one "training session" (approximately 30 minutes). You and your child can decide if they would like to continue to play the game for a longer time. Between the post-intervention and follow-up visits, your child will be asked to fill out a brief survey (2 minutes) every day for 30 days. At the 1-month follow-up visit, one parent/legal guardian will also be asked to fill out some questionnaires, which takes about 60 minutes to complete.

Why might you choose to have your child to take part in this study?

We cannot promise any direct benefits to your child from taking part in this research study. However, your child may have fun playing virtual reality video games. Others with traumatic brain injuries may benefit in the future from what we learn in this study.

Why might you choose NOT to have your child to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. Important risks and possible discomforts to know about include (but are not limited to) symptoms related to Virtual Reality motion sickness, such as headaches, nausea, blurred vision, hurting eyes, dry eyes, tiredness, mental stress/fatigue.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?" Other things to consider are time commitment and transportation (if applicable) to participate in this study.

What other treatments or procedures are available for your child's condition?

The virtual reality games provided in this study are designed to supplement your standard care and/or therapies. Your child will continue to receive standard of care regardless of your participation in this study.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Stacy Suskauer is the person in charge of this research study at Kennedy Krieger Institute. You can call her at 443-923-9440. You can also call Dr. Stacy Suskauer if you have questions about the scheduling of appointments or study visits. You can also reach out to Tyler Busch at 443-885-0288.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. If you are a participant at Kennedy Krieger Institute, you may contact the Kennedy Krieger Institute Office of Human Research Administration at ohra@kennedykrieger.org. You may also contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Study visits will take place at one of four locations, depending on whether/where your child is currently receiving care at Kennedy Krieger. Below are details about these locations and emergency contact information.

- 716 N Broadway, Baltimore, MD 21205
    - In the event of an emergency dial 911
- 1750 E Fairmount Ave, Baltimore, MD 21231
    - In the event of an emergency dial 911
- 707 N Broadway, Baltimore, MD 21205
    - Kennedy Krieger Institute emergency phone number: 410-522-2395
- 801 N Broadway, Baltimore, MD 21205
    - Kennedy Krieger Institute emergency phone number: 410-522-5580

Detailed Information

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.

Why is this research study being done?

We are doing this research to find out if our virtual reality games will help kids regain skills after they have had a brain injury. We want to know how they work for different kids, so you and your child will be asked some questions.

Who will take part in this research?

We are asking you to give permission for your child to take part in this research study because your child is between 6 and 17 years old with the diagnosis of traumatic brain injury in the past 18 months. About 11 people will take part in this research study, all at Kennedy Krieger Institute. The National Institutes of Health is paying for this research to be done.

What will happen in this research study?

If you provide permission for your child to take part in this study, we will ask you to sign this consent form before we perform any study procedures.

The following study steps will be following if your child participates in this study:

- **Visit 1: Baseline Assessment (about 1 hour):**

- Your child will complete a standard cognitive and attention assessment using virtual reality equipment, computer, and iPad as well as several surveys with a researcher.
- After this visit, your child will be assigned by chance (like tossing a coin), to play one of two virtual reality games we developed. One game we are testing to see if it can help children regain skills (intervention game), and the other game is not expected to influence skills (placebo game). No matter which game your child plays, he/she will continue to receive the standard care for their condition.

- **Between Visit 1 and Visit 2:**
  - You child will play one training session (approx. 30 minutes).
    - You and your child can decide if they would like to continue playing the game for longer.
    - Breaks are available upon request any time
  - We will ask your child some questions about his/her experience after the first game session.
- **Visit 2: Post Assessment (about 1 hour):**
  - After completing the training session, your child will complete the same set of computer tasks and paper assessment as Visit 1.
  - **Brief Survey Between Visit 2 and Visit 3 (about 2 minutes per day for 30 days):**
    - During a 30-day period, a researcher will ask your child to complete a brief survey via email or phone call (depending on your and your child's preference) every day to see how your child is doing after playing the VR game.
  - **Visit 3: Follow-Up Visit (about 1 hour).**
    - You will be scheduled to return to the hospital approximately 1-month following Visit 2.
      - Your child will complete the same set of computer tasks as Visit 1 plus some additional paper questionnaires with a researcher.
      - One parent/legal guardian will complete several paper questionnaires, which will take about 30 minutes.

Your child's medical records will be reviewed by the study team. A notation that your child is taking part in this research study may be made in your child's electronic medical record. Information from the research that relates to your child's general medical care may be included in the record. Please ask your child's study doctor if you have any questions about what information will be included in your child's electronic medical record.

How may we use and share your samples and health information for other research?

The data and information we collect in this study may help advance other research. If your child joins this study, we may remove all information that identifies your child (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information back to your child. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Sharing data is part of research and may increase what we can learn from each study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners

- through government or other databases/repositories

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB), a group of people that reviews human research studies, is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

The use of your data is required for participation in this research study. If you are not comfortable with the use of your data in future research without further consent, you should not participate in this study.

Will you get the results of this research study?

You and your child's doctor should not expect to get information about the results of the research study or the results of your child's individual participation in the research study. We will study information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your child's health. If this happens, we may contact you to find

out if you would like to learn more. However, even if we find something important to your child's health, we cannot guarantee that you will be contacted.

What are the risks and possible discomforts from being in this research study?

We believe that there is very little chance that bad things will happen as a result of being in this study.

- It is possible that your child might feel motion sickness using the virtual reality goggles. Possible symptoms include (but not limited to) headaches, nausea, blurred vision, hurting eyes, dry eyes, and souring muscles.
- Your child might also experience stress and mental/physical fatigue while completing the training/tasks in the virtual environment.
- It is possible that your child could feel upset when answering questions about their experiences with the virtual reality game.
- It is possible that you or your child might feel stress, upset, or fatigue when completing the computer/paper tasks or questionnaires.
    - It may be more likely that you or your child finds the questions a little boring.
    - If you or your child do find any of the questions or tasks upsetting or don't want to answer a question, you don't have to, and a researcher will be available to talk with you about this.
- On rare circumstances, the computing devices used to deliver virtual reality games or other computer tasks might malfunction due to hardware and/or software failure.
- Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.
- There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

You and your child may not benefit directly from taking part in this research study. Possible indirect benefits might be that your child may gain skills playing the virtual reality games. Your child might have fun playing with electronics using this new technology. We might also learn something about traumatic brain injuries that could help future patients and other people with the same condition.

What other treatments or procedures are available for your condition?

You may choose to not participate in this study. This will not affect your standard care.

Can you still get medical care within Kennedy Krieger Institute if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Kennedy Krieger Institute now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will receive a total amount of remuneration up to $310 upon completion of the study procedures.

- We will provide your child in the form of a gift card with $40.00 for completing Visit 1.
- We will provide your child in the form of a gift card with an additional $50.00 for completing the designated VR game-playing and Visit 2
- We will provide your child in the form of a gift card with an additional $60 for completing the entire 30-day daily survey (pro-rated if completed fewer than 30 surveys)
- We will provide your child in the form of a gift card with an additional $80.00 for completing the Visit 3.
- We will provide the participating parent/legal guardian in the form of a gift card with $80 for completing the parental questionnaires during Visit 3.

There will be no reimbursement for research-related costs such as travel, parking, or meals, etc. You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins and Kennedy Krieger exceed $600 per year, Johns

Hopkins and Kennedy Krieger will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

We may use your child's data and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you or your child if your data or information are used for this purpose.

What will you have to pay for if your child take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services your child would have received even if s/he did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from your child taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

Subject Injury/Indemnification

What treatment costs will be paid if you are injured in this study?

Kennedy Krieger and Johns Hopkins do not have a program to pay you if you are hurt or have other bad results from being in the study.

Kennedy Krieger, Johns Hopkins, and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

If you take part in this research study, how will we protect your privacy?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine, Kennedy Krieger Institute, and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University, the Johns Hopkins Applied Physics Laboratory, or Kennedy Krieger Institute. Additionally, we may share your information with other people at Johns Hopkins or Kennedy Krieger Institute, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
We have rules to protect information about your child. Federal and state laws and the federal medical Privacy Rule also protect your child's privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.
The research team working on the study will collect information about your child. This includes things learned from the procedures described in this consent form. They may also collect other information including your child's name, address, date of birth, and information from your child's medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your child's identity and that your child is in the research study. Other people at Johns Hopkins and Kennedy Krieger Institute, particularly your doctors, may also see or give out your child's information. We make this information available to your child's doctors for your child's safety.

People outside of Johns Hopkins or Kennedy Krieger Institute may need to see or receive your child's information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your child's information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your child's information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins or Kennedy Krieger Institute who receive your child's information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your child's

information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your child's information has no time limit. You may revoke (cancel) your permission to use and disclose your child's information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your child's information, your child's part in this study will end and no further information about your child will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

All appropriate procedures will be followed to ensure that your personal information remains confidential. Your paper records will be kept in a locked cabinet in a locked office. Electronic files with identifying information will be password protected. Your responses to questionnaires will be stored in the Johns Hopkins REDCap, a secure web application. Only staff, researchers, and external collaborators to this study will have access to the data.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate

does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

I. Assent

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant (Print Name) Date/Time

Signature of Person Obtaining Consent (Print Name) Date/Time

Signature of Parent/Legal Guardian/Court-Appointed Representative (Print Name) Date/Time

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).