## Title of research study: (Insert title of research study here with VT IRB protocol number, if applicable.)

## Principal Investigator: (Required: insert name of principal investigator as well as contact information, phone number and e-mail required.)

**Other study contact(s):** *(Optional: insert names as well as contact information.)*

**Key Information:** The following is a short summary of this study to help you decide whether or not to provide permission for your child be a part of this study. More detailed information is listed later on in this form. *(This is a required section according to the revised Common Rule. Use plain language, short sentences, and avoid technical terms and discipline-specific language in order to keep all sections at the reading level of the intended study population. Please include only a brief summary in this key information section. This section can be formatted in several different ways. Investigators are welcome to use the headings format, as outlined below, or use an alternative format listed within the following link:* Other Examples of Key Information*.*

**Why is my child being invited to take part in a research study?**

We invite your child to take part in a research study because *(Fill in the circumstance that makes subjects eligible for the research. For example: Your child is between the ages of 12-15 and has never experienced virtual reality.)*

**What should I know about my child being in a research study?**

● Someone will explain this research study to you and your child

● Whether or not you provide permission is up to you

● You can choose not to provide permission

● You can provide permission and later change your mind

● Your decision will not be held against you

● You can ask all the questions you want before you decide

**Why is this research being done?**

*(Tell the parent/legal guardian/legally authorized representative the purpose of the research. Summarize the background of the research problem. Summarize any potential benefits to society or others. For example: The purpose is to figure out the best virtual reality image loading speed for children in this age group. When the image loading speed is too slow, the experience is jerky. Fixing this will allow more  people to feel like they have stepped into another world.)*

**How long will the research last and what will my child need to do?**

We expect that your child's participation in this research study will last \_\_\_\_\_\_\_. *(Include hours/days/weeks/months/years, until a certain event. If the involvement will require more than one visit it is important to include that information as well. A brief mention of where the testing will be done should also be included. For example: For a total of four hours across two separate lab visits. All procedures will be conducted in the Example Lab on the Virginia Tech campus in Blacksburg, VA.)*

Your child will be asked to \_\_\_\_\_\_\_\_\_\_*(Include a high level summary of the procedures that will be done. For example: Visit the Virtual Reality Lab twice, and each visit will be two hours long. These visits will be about one week apart. At each visit, your child will be asked to wear a virtual reality headset and explore a room. Afterwards, your child will fill out questionnaires about their experience.)*

More detailed information about the study procedures can be found under ***“What happens if I  say yes, I want my child to be in this research?”***

**Is there any way being in this study could be bad for my child?**

*(This beginning section of the parent permission form should briefly identify the most important risks, e.g., similar to the information that a physician might deliver in the clinical context when telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by the child participating in the study. If risks are very minor such as filling out an online questionnaire, say “Risks are no more than would be expected in everyday life.” For example: There is a risk that your child might become nauseous or dizzy.)*

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for my child? (Detailed Risks)”***

**Will being in this study help my child in any way?**

*(This beginning section of the parent permission form should identify one or more likely benefits resulting from participation in the study. In doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the permission form.)*

*(Include if there are benefits to participation. Otherwise delete.)* We cannot promise any benefits to your child or others from their taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_. *(First describe any direct benefits to the subject, then any potential benefits to society or others, such as contributing to the knowledge base in your field. If benefits from participation may not continue after the research has ended, describe them here. Do not list any form of payment for participation, as this is not considered a benefit.)*

*(Include for a study with no benefits to participation. Otherwise delete.)* There are no benefits to your child from their taking part in this research. We cannot promise any benefits to others from their taking part in this research. However, possible benefits to others include\_\_\_\_\_\_\_\_\_. *(Describe any potential benefits to society or to others, such as contributing to the knowledge base in your field. Research payment for participation is not considered a benefit. For example: the virtual reality industry gaining a better understanding of what the minimum  frame loading speed should be.)*

**What happens if I do not want my child to be in this research?**

Taking part in research is completely up to you and your child. You can decide to provide permission or not provide permission to participate.

*(Include if there are alternatives other than participating. Otherwise delete.)* Instead of being in this research study, other choices for your child may include *(List alternative procedures)*

*(For clinical trials, describe the options that you would normally offer a patient. If applicable, include supportive care as an option)*

## Detailed Information: The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt your child, talk to the research team at *(Insert contact information for the research team.)*

This research has been reviewed and approved by the Virginia Tech Institutional Review Board (IRB). You may communicate with them at 540-231-3732 or irb@vt.edu if:

* You have questions about your childs’ rights as a research subject
* Your questions, concerns, or complaints are not being answered by the research team
* You cannot reach the research team
* You want to talk to someone besides the research team to provide feedback about this research

## How many people will be studied?

We plan to include about \_\_\_\_\_ people in this research study.

*(If multisite study, state:)*

We plan to include about \_\_\_\_\_ people at this location out of \_\_\_\_\_ people in the entire study nationally *(or internationally).*

## What happens if I say yes, I want my child to be in this research?

*(Tell the parent/legal guardian/legally authorized representative what to expect using plain language. Whenever appropriate include the following items:)*

* *If procedures require more than one session, prepare a timeline, chart, or diagram to accompany descriptions of procedures and tests*
* *The length and duration of visits and procedures*
* *With whom will the subject interact*
* *Where the research will be done*
* *When the research will be done*
* *List experimental procedures and therapies that the subject will experience*
* *How often procedures or study activities will be performed*
* *All devices and equipment that will be used, including drawings or photos of non-routine devices that the subject will interact with or wear.*
* *If blood will be drawn, indicate the amount (in US units) and frequency*
* *If saliva or other specimens will be obtained and for what purpose*
* *If subjects might be students, explain which procedures are also part of the course or class and which are part of the research study only. If the only procedure is giving consent for the researcher to analyze course work or grades for research and publication purposes, state that clearly.*
* *When applicable, indicate that the subject will be contacted for future research, and if so, whether that is related to the current study or for new studies.*

## What happens if I say yes, but I change my mind later?

You can withdraw your permission for your child’s participation in this research at any time, for any reason, and it will not be held against you.

*(Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete.)*If you decide you no longer want your child to participate in the research, *(Describe the adverse consequences.)*

If you decide you no longer want your child to participate in the research, contact the investigator so that the investigator can *(Describe the procedures for orderly termination by the subject, if any.)*

*(Describe what will happen to data collected to the point of withdrawal. Describe whether the parent/legal guardian/legally authorized representative will be asked to explain the extent of their withdrawal of their permission and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a parent/legal guardian/legally authorized representative may wish to withdraw permission for an experimental procedure because of unacceptable side effects, but may permit the child to undergo follow-up procedures and data collection.)*

## Is there any way being in this study could be bad for my child? (Detailed Risks)

*(The risks of procedures may be presented in a table form.)*

*(Describe each of the following risks, as appropriate. If known, describe the probability and magnitude of the risk. For each risk, also describe how the researcher is minimizing or managing the risk and/or how the subject should respond if the risk were to occur.)*

* *Physical risks (e.g., potential for pain, discomfort, infection. If any imaging is being performed, discuss radiation exposure and associated physical risks)*
* *Psychological risks (e.g., potential for stress, fear, discomfort, embarrassment)*
* *Privacy risks (e.g., potential for personal information being accessed, used or disclosed without the subjects’ knowledge or consent, breach of confidentiality/security)*
* *Legal risks (e.g., potential for disclosure of illegal activity, negligence)*
* *Social risks (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
* *Economic risks (e.g., potential for individuals to lose access to economic services, employment, insurability)*

*(If no risks have been identified state:)*There are no known risks to participating in this study.

*(Include for research that may result in additional costs to the subjects. Otherwise delete.)* Taking part in this research study might lead to added costs to you. *(Describe what these costs are and whether they will be reimbursed. Examples could include travel, child care.)*

## What happens to the information collected for the research?

We will make every effort to limit the use and disclosure of your child’s personal information, including research study and medical records, only to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your child’s information include the IRB, Human Research Protection Program, and other authorized representatives of Virginia Tech. *(Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration [FDA], when the research if FDA-regulated, the Department of Health and Human Services [HHS], when the research is conducted or funded by HHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.)*

*(Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.)*

*(If data, including specimens, will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, how long the data or specimens will be retained, and whether they will include identifiers.)*

*(If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:)*

If identifiers are removed from your child’s private information or samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional permission.

*OR*

*(This option will rarely be used.)* Your child’s information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

*(Please describe the planned uses for the research results. Revise the following statement as appropriate.)* The results of this research study may be presented in summary form at conferences, in presentations, reports to the sponsor, academic papers, and as part of a thesis/dissertation.

*(Include if a HIPAA authorization is required. Otherwise delete.)* Federal law provides additional protections of your child’s medical records and related health information. These are described in an attached document.

## Can my child be removed from the research without my OK?

*(Include for research where this is a possibility. Otherwise delete.)*The person in charge of the research study or the sponsor can remove your child from the research study without your approval. Possible reasons for removal include *(Describe reasons why the subject could be withdrawn, if appropriate.)*

*(Include for research where this is a possibility. Otherwise delete.)*We will tell you and your child about any new information that might affect their health, welfare, or choice to stay in the research.

## What else do I need to know?

*(Include if this project is funded. Otherwise delete.)* This research is being funded by *(Insert name(s) of funder)*.

*(If as a result of the research project, the investigator determines that the subject should seek counseling or medical treatment, a list of local services should be provided.)*

*(If applicable, inform subjects:)*Any expenses accrued for seeking or receiving medical or mental health treatment will be your responsibility and not that of the research project, research team, or Virginia Tech.

*(Describe whether there is payment (monetary or nonmonetary) for participation. If so, state the amount(s), reason(s), method(s), and timing of payments and also whether the child and/or the parent/legal guardian/legally authorized representative will receive the payment. Otherwise delete.)* If you provide permission for your child to take part in this research study, we will reimburse *(indicate you/your child)* $\_\_\_\_\_\_\_\_ *(indicate amount)* for expenses *(itemize)*. *(indicate You/Your child)*will also receive $\_\_\_\_\_ for (*your/their)* time and effort. *(If you will pay additional incentives for participation, add:)*In addition, if your child completes the study, *(indicate you/your child)*will receive $\_\_\_\_.*(Include descriptions of any additional incentives for participation. Include amounts and schedule. Indicate if the amount is pro-rated for research visit completion. For complicated payment plans, include a chart. Tell the parent/legal guardian/legally authorized representative the method of payment, such as ClinCard, gift cards [specify business], cash, check.)*

*(If compensation will include a drawing, include the following. Odds are usually described as “one in X”, depending on the number of subjects and the number of drawings.)**(indicate You/Your child)*can choose to be included in a drawing for $\_\_\_\_\_. The odds of receiving $ \_\_\_\_\_ are one in \_\_\_. *(depending on the total number of subjects)*

*(Include for Department of Defense [DOD] research that includes military personnel where subjects will be paid – this is rare. Otherwise delete.)*Military personnel should check with their supervisor before accepting payment for participation in this research.

*(Future use for commercial purposes, include when applicable and alter to match the type of data being collected. Otherwise delete. If you do not inform subjects about this possibility, you will not be able to use information and samples for this purpose without additional consent.)*Your child’s information and samples (both identifiable and de-identified) might be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *(or replace with plans when using identifiable information/samples)* to tell you, or to pay you, or to give any compensation to you or your family.

*(Select either “will” or “will not”. When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions)*We *(will/will not)*offer to share your child’s individual test results with you *(and/or)* your child. You may accept or decline these results.

*(Omit the signature page if there is no written documentation of consent. If electronic consent will be obtained, add the text that will be used in place of the signature page. If verbal consent will be obtained, include the script that will be used to obtain consent.)*

**Signature Block for Capable Adult** *(If the research: 1. Does not involve greater than minimal risk or 2. Does involve greater than minimal risk but presents the prospect of direct benefit to the individual subject, the IRB may find that the permission of one parent/legal guardian/legally authorized representative is sufficient.)*

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| --- | --- | --- |
| Your signature documents your permission for your child to take part in this research. We will provide you with a signed copy of this form for your records. | | |
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| Signature of parent/legal guardian/legally authorized representative |  | Date |
|  |  | |
| Printed name of parent/legal guardian/legally authorized representative |
|  |  |  |
| Signature of person obtaining permission |  | Date |
| Printed name of person obtaining permission |  |  |

*(If the research is greater than minimal risk and offers no prospect of direct benefit to the individual subject but is likely to yield generalizable knowledge about the subject’s disorder or condition, a second parent is required to sign the permission form, unless the second parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has legal responsibility for the care and custody of the child. Otherwise delete)*

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| --- | --- | --- |
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| Signature of second parent/legal guardian/legally authorized representative |  | Date |
|  |  | |
| Printed name of second parent/legal guardian/legally authorized representative |
|  |  |  |
| Signature of person obtaining permission |  | Date |
| Printed name of person obtaining permission |  |  |