

Options for the Consent Form: Key Information Section

Regulation:

“Except for broad consent obtained in accordance with paragraph (d) of this section:

- 1) Informed consent must begin with a concise and focused presentation of key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- 2) Informed consent as a whole must present information in a sufficient detail relating to the research, and must be organized and presented in a way that does not merely provided lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representatives understanding of the reasons why one might or might not want to participate.”

(Src: Federal Register/Vol. 82, No. 12/Thursday, January 19, 2017/Rules and Regulations Pages 117-118)

For researchers across the United States, the federal regulations governing human research changed on January 21, 2019. One of the changes is that the consent form is required to provide the key study information at the beginning of the consent form. This change is intended to increase the prospective subject's understanding of the study they have been invited to join.

There are different ways that you can present this information:

Type	Example	To help guide your selection, please consider using the following formats for these types of studies
Headings	Example 1 Detailed Instructions	<ul style="list-style-type: none"> ● Involves multiple procedures ● Involves multiple subject populations who are encountering different procedures ● Overall form is longer
Bullets	Example 2	<ul style="list-style-type: none"> ● Involves multiple procedures ● Involves multiple subject populations who are encountering the same procedures
Paragraph	Example 3	<ul style="list-style-type: none"> ● Involves a single procedure ● Involves a single subject population ● Overall form is shorter

[Jump Back to the Landing Page](#)

Example 1: Headings

Title of research study: IRB #19-##### The Relationship between Image Frame Loading Speed and Immersion in Virtual Reality Experiences

Principal Investigator: Dr. Zircon Peridot 540-231-##### or demo_zircon@vt.edu

Other study contact:

- Ruby Basalt (540-231-##### or demo_vr_lab@vt.edu)
- Mica Slate (540-231-##### or demo_mica@vt.edu)

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a student between the ages of 18-25 who has never experienced virtual reality or you are a resident of Montgomery County, VA who is 18 years old or older.

What should I know about being in a research study?

- Someone will explain this research study to you
- Whether or not you take part is up to you
- You can choose not to take part
- You can agree to take part 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?

The purpose is to figure out the best image loading speed for the general public. 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 I need to do?

For students, we expect that your participation in this research study will last for total of four hours. You will be asked to visit the Virtual Reality Lab twice, and each visit will be two hours long. At each visit, you will be asked to wear a virtual reality headset and explore a room. Afterwards, you will fill out questionnaires about your experience.

For residents, we expect that your participation in this research study will last for total of six hours. You will be asked to visit the Virtual Reality Lab twice, and each visit will be three hours long. At each visit, you will be asked to wear a virtual reality headset and explore a room. Afterwards, you will fill out questionnaires about your experience. You will also participate in an audio recorded focus group.

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

Is there any way being in this study could be bad for me?

There is a risk that you 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 me? (Detailed Risks)”***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the virtual reality industry gaining a better understanding of what the minimum frame loading speed should be.

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

Taking part in research is completely up to you. You can decide to participate or not to participate.

If you are a student, the decision whether to participate or not participate will have no effect on your grades or relationship with Virginia Tech.

[Jump Back to the Landing Page](#)

Example 2: Bullets

Title of research study: IRB #19-##### The Relationship between Image Frame Loading Speed and Immersion in Virtual Reality Experiences

Principal Investigator: Dr. Zircon Peridot 540-231-##### or demo_zircon@vt.edu

Other study contact:

- Ruby Basalt (540-231-##### or demo_vr_lab@vt.edu)
- Mica Slate (540-231-##### or demo_mica@vt.edu)

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a student between the ages of 18-25 who has never experienced virtual reality or you are a resident of Montgomery County, VA who is 18 years old or older.

What should I know about being in a research study?

- Someone will explain this research study to you
- Whether or not you take part is up to you
- You can choose not to take part
- You can agree to take part and later change your mind
- Your decision will not be held against you
- You can ask all the questions you want before you decide

What should I know about this research study?

- The purpose is to figure out the best image loading speed for the general public. 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.
- We expect that your participation in this research study will last for total of four hours. You will be asked to visit the Virtual Reality Lab twice, and each visit will be two hours long. At each visit, you will be asked to wear a virtual reality headset and explore a room. Afterwards, you will fill out questionnaires about your experience. More detailed information about the study procedures can be found under “What happens if I say yes, I want to be in this research?”

- There is a risk that you 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 me? (Detailed Risks)”
- There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the virtual reality industry gaining a better understanding of what the minimum frame loading speed should be.
- Taking part in research is completely up to you. You can decide to participate or not to participate. If you are a student, the decision whether to participate or not participate will have no effect on your grades or relationship with Virginia Tech.

[Jump Back to the Landing Page](#)

Example 3: Paragraph

Title of research study: IRB #19-#### The Relationship between Image Frame Loading Speed and Immersion in Virtual Reality Experiences

Principal Investigator: Dr. Zircon Peridot 540-231-#### or demo_zircon@vt.edu

Other study contact:

- Ruby Basalt (540-231-#### or demo_vr_lab@vt.edu)
- Mica Slate (540-231-#### or demo_mica@vt.edu)

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

We invite you to take part in a research study because you are a student between the ages of 18-25 who has never experienced virtual reality.

What should I know about being in a research study?

- Someone will explain this research study to you
- Whether or not you take part is up to you
- You can choose not to take part
- You can agree to take part and later change your mind
- Your decision will not be held against you
- You can ask all the questions you want before you decide

What should I know about this research study?

The purpose of this study is to figure out the best image loading speed for the general public. 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. We expect that your participation in this research study will last two hours. You will be asked to wear a virtual reality headset and explore a room. Afterwards, you will fill out questionnaires about your experience. (More detailed information about the study procedures can be found under *“What happens if I say yes, I want to be in this research?”*.) There is a risk that you 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 me? (Detailed Risks)”*.) There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the virtual reality industry gaining a better understanding of what the minimum frame loading speed should be. Because you are a student, the decision whether to participate or not participate will have no effect on your grades or relationship with Virginia Tech.

[Jump Back to the Landing Page](#)

Detailed Instructions For Headings Style

Why am I being invited to take part in a research study?

We invite you to take part in a research study because _____. *(Fill in the circumstance or condition that makes subjects eligible for the research. For example: you are a student between the ages of 18-25 who has never experienced virtual reality.)*

What should I know about being in a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part 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 subject 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 image loading speed for the general public. 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 I need to do?

We expect that your participation in this research study will last _____. *(Include hours/days/months/weeks/years, until a certain event. For example: two hours.)*

You will be asked to _____. *(Include a high level summary of the procedures that will be done. For example: You will be asked to wear a virtual reality headset and explore a room. Afterwards, you will fill out questionnaires about your experience.)*

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

Is there any way being in this study could be bad for me?

(This beginning section of the consent form should briefly identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project with a particular emphasis on how those risks are changed by 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 you 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 me? (Detailed Risks)”**

Will being in this study help me in any way?

(This beginning section of the consent 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 consent document.)

(Include if there are benefits to participation. Otherwise delete.) We cannot promise any benefits to you or others from your 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 monetary reimbursement for participation: this is not a benefit.)*

(Include for a study with no benefits to participation. Otherwise delete.) There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your 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. Monetary reimbursement for participation is not a benefit. For example: the virtual reality industry gaining a better understanding of what the minimum frame loading speed should be.)*

[Include for research involving prisoners.] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

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

Taking part in research is completely up to you. You can decide to participate or not to participate.

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

(Include if some or all of the subjects might be Virginia Tech students. Otherwise delete.) If you are a student, the decision whether to participate or not participate will have no effect on your grades or relationship with Virginia Tech.