

**CONSENT FORM**

(SAMPLE: Intended for general public and English is first language)

(6th Grade Flesch-Kincaid score, Flesch Reading level = 75)

**STUDY TITLE: (Insert project title here.)**

**INTRODUCTION**
This form is to help you decide if you want to say "YES" or "NO" to be part of this Study (also may be known as research, research study, or a project). It also records your "YES" if you agree. To agree is also called “Consent”. (Include the Name or Title of the Research Project and place in which the proposed research will be conducted.)

**WHAT IS THIS STUDY ABOUT?**
This study is about (.... a non-technical, plain language explanation of the testing protocol and exactly what is expected of the subject, including a description of which procedures are experimental and their accepted, non-experimental alternatives...).

If you say "YES," you will be part of the study for (..duration of participation...) at (...location of participation...).
About (Insert Number) people of (...similarly situated subjects...) will also be joining this study.

(Include a plain language [6th grade level and/or define terms] description of whatever you are researching, purpose of the research, e.g., the effects of independent variable on dependent variable, A detailed description of what participation involves [e.g., activities, procedures, duration], Information on number of participants involved....).

**WHO CAN BE IN THIS STUDY?**
You can join if you (....list of Inclusionary criteria....).

You should not join if (....list of Exclusionary criteria....).

**RISKS (Discomforts/Problems)**
There can be risks if you join this study. A risk is a problem or “discomfort” that can happen when you are in a study. There may be a risk of (. . . clear description of all foreseeable risks, discomforts, or undesirable outcomes....)The person running the study will try to keep your risk as low as possible, but we still want you to know that it is possible. (List ways that risk is being reduced if applicable e.g., providing padding, using a licensed nursed, removing all linking identifiers...) In any study like this one, there could also be risks we don’t know about yet.

**BENEFITS (Good)**
By being part of this study, you may (...example of benefit other than payment, e.g., a free eyesight exam. ). Others may also (...example of how others may benefit. e.g. better way to treat PTSD, etc...)

**COSTS & PAYMENTS**
You may have costs while in this study. Some costs include (...costs, inconvenience, etc., such as parking fees...).

You will be paid [Insert Payment amount] to help with the costs listed above.

[OR] You will not receive any form of payment for being in this study.

**NEW INFORMATION**
If we find new information that might change your mind about joining, we will tell you.

**FUTURE USE OF YOUR INFORMATION**
We will not share your name or any private information that can be used by others to find out who you are. The results of this study may be used in reports, presentations, and publications (like classes or journals for doctors or nurses).

This information may be also be used for future research.

OR

We do not plan to use this information for future studies unless you agree by signing a new consent.

**KEEPING YOUR INFORMATION PRIVATE**
We will keep your information private unless, for some reason, the law says we must share it. Other ways that we plan to keep your information private include (insert how)

**CLINICAL RESEARCH (This only applies to clinical research, erase for all other research)**

Your clinically relevant research results (will or will not be) disclosed to you. (if so describe under what conditions).

**LEAVING THE STUDY**
This study is voluntary. This means you can say "NO" or walk away at any time, even if you said "YES" before. You will not lose benefits that you already have. Leaving the study will not affect your rights or your relationship with Regent University. [If applicable: The researchers reserve the right to withdraw your participation in this study, at any time, if they observe potential problems with your continued participation.]

**IF YOU GET HURT OR BECOME ILL**Agreeing to be a part of this study does not mean you give up any rights. You still keep all of your legal rights. Regent University does not pay for doctor or hospital bills, insurance, or free medical care, and they do not give money or pay you back for any costs due to being hurt or sick. If you are hurt or feel sick because of this study, or if you have any health questions or concerns, seek proper care first (if needed). You can also contact (...the responsible principal investigator or investigators at the following email/phone numbers.... note all emails and phone numbers must be REGENT ones, not personal numbers or emails) or the IRB chair at irb@regent.edu.

**VOLUNTARY CONSENT**
“Voluntary” means that it is your choice and “Consent” means you agree to be in the study. No one should make you feel like you must be in the study. If you do want to be in the study, you can sign this form. By signing this form, you are saying you understand what this study is about and what the risks are.

You should have all your questions answered before you sign the consent. If you have questions any time after you sign, you can ask the researcher (person running the study).

**Researcher Name** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Phone** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(...include investigators names, academic degree, and sponsoring faculty member’s Regent phone number....).

If you have any questions or concerns that you would like to talk about with someone else, you may also contact the IRB chair at irb@Regent.edu or 757-352-5010.

(Consent Options: Choose and retain the appropriate option below. Remove others.)

**Online Consent (Implied via Survey Completion):**Completion of the online survey confirms voluntary participation in this study by an individual at least 18 years of age.

**Verbal Consent (Used for Remote Interviews via Zoom or Phone):**For interviews conducted remotely, informed consent will be reviewed verbally prior to participation. Verbal agreement to participate will be documented by the researcher in study notes or through an audio/video recording. No signature is required.

*Note: This study has been approved by the Regent University IRB to use verbal consent for remote interviews when obtaining a signed form is not practicable and the study meets the criteria for a waiver of documentation of consent under 45 CFR 46.117(c)(2).*

**In-Person Consent (Signed):**
Signing below indicates agreement to participate in this study.

**You will be given a copy of this consent to keep for your records.**

|  |  |
| --- | --- |
| Subjects Printed Name and Signature | Date |
| Parent / Legally Authorized Representative’s Printed Name & Signature (If applicable) | Date |
| Witness’ Printed Name and Signature (if applicable) | Date |

INVESTIGATOR’S STATEMENT

I certify that I have explained to this subject the nature and purpose of this research, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to human subjects and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

|  |  |
| --- | --- |
| Investigator’s Printed Name & Signature | Date |