

**INFORMED CONSENT DOCUMENT**

 **(SAMPLE)**

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

**INTRODUCTION**

The purposes of this form are to give you information that may affect your decision whether to say YES or NO to participation in this research, and to record the consent of those who say YES. (Include the Name or Title of the Research Project and place in which the proposed research will be conducted.)

**DESCRIPTION OF RESEARCH STUDY**

Several studies have been conducted looking into the subject of (...plain language description of whatever you are researching, purpose of the research, e.g., the effects of independent variable on dependent variable...).

If you decide to participate, then you will join a study involving research of (.... 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, then your participation will last for (...duration of participation...) at the (...location of participation...). Approximately (...number...) of (...similarly situated subjects...) will be participating in this study.

**EXCLUSIONARY CRITERIA**

To participate you should (....description of demographics or screening instrument or questionnaire(s)....). To the best of your knowledge, you should not have (....list of exclusionary criteria....) that would keep you from participating in this study.

**RISKS AND BENEFITS**

RISKS: If you decide to participate in this study, then you may face a risk of (. . . clear description of all foreseeable risks, discomforts, or undesirable outcomes....). The researcher tried to reduce these risks by (...e.g., providing padding, using a licensed nursed, removing all linking identifiers...). And, as with any research, there is some possibility that you may be subject to risks that have not yet been identified.

BENEFITS: The main benefit to you for participating in this study is (...example of benefit other than payment, e.g., a free eyesight exam. ). Others may benefit by (...example...).

**COSTS AND PAYMENTS**

The researchers want your decision about participating in this study to be absolutely voluntary. Yet they recognize that your participation may pose some (...costs, inconvenience, etc., such as parking fees...). In order to (...e.g., help defray your costs) you will receive (...e.g., five dollars, or "no payment...) to help defray incidental expenses associated with participation.

[OR]

The researchers are unable to give you any payment for participating in this study.

**NEW INFORMATION**

If the researchers find new information during this study that would reasonably change your decision about participating, then they will give it to you.

**FUTURE RESEARCH**

The researchers (may remove identifiable information from your results or will not) use this information for future research without further informed consent.

**CONFIDENTIALITY**

All information obtained about you in this study is strictly confidential unless disclosure is required by law. The results of this study may be used in reports, presentations and publications, but the researcher will not identify you.

**WITHDRAWAL PRIVILEGE**

It is OK for you to say NO. Even if you say YES now, you are free to say NO later, and walk away or withdraw from the study ‑‑ at any time. [If applicable] Your decision will not affect your relationship with Regent University, or otherwise cause a loss of benefits to which you might otherwise be entitled. [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.]

**COMPENSATION FOR ILLNESS AND INJURY**

If you say YES, then your consent in this document does not waive any of your legal rights. However, in the event of (..harm, injury, or illness...) arising from this study, neither Regent University nor the researchers are able to give you any money, insurance coverage, free medical care, or any other compensation for such injury. In the event that you suffer injury as a result of participation in this research project, you may 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 current IRB chair at irb@regent.edu at Regent University, who will be glad to review the matter with you.

**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).

**VOLUNTARY CONSENT**

By signing this form, you are saying several things. You are saying that you have read this form or have had it read to you, that you are satisfied that you understand this form, the research study, and its risks and benefits. The researchers should have answered any questions you may have had about the research. If you have any questions later on, then the researchers should be able to answer them:

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

If at any time you feel pressured to participate, or if you have any questions about your rights or this form, then you should contact the current IRB chair, at irb@regent.edu or 757-352-5010.

And importantly, by signing below, you are telling the researcher YES, that you agree to participate in this study. The researcher should give you a copy of this form for your records.

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| --- | --- |
|  **Subject's Printed Name & Signature**  | **Date** |
|  **Parent / Legally Authorized Representative’s Printed Name & Signature (If applicable)**  | **Date** |
| **Witness' Printed Name & 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.

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|  **Investigator's Printed Name & Signature** | **Date** |