

[For nonrandomized and randomized studies:]

If you take part in this study, you will have the following tests and procedures:

[List procedures and their frequency under the categories below. Identify experimental procedures as such. For randomized studies, list the study groups and under each describe categories of procedures. Include where a subject will be, e.g., at home, at school, at a hospital, etc. If the research question(s) or aims include a comparison of interventions, list all procedures, even those considered standard.]

- **Procedures that are part of your regular care/education/etc. and may be done even if you do not join the study.**
- **Standard procedures being done because you are in this study.**
- **Procedures that are being tested in this study.**

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for _____ (MONTHS, WEEKS, OR UNTIL A CERTAIN EVENT).

[Where appropriate, state that the study will involve long-term follow-up.]

The researcher may decide to take you off this study if _____.

[List circumstances, such as in the participant's medical best interest, funding is stopped, subject is distressed, inappropriate information is being revealed, new information is available, etc.]

You can stop participating at any time. [If applicable:] However, if you decide to stop participating in the study, we encourage you to talk to the researcher (and your regular doctor, psychologist, teacher, etc., first.)

[Describe any serious consequences of sudden withdrawal from the study.] **WHAT ARE THE RISKS OF THE STUDY?**

While in the study, you are at risk in these ways. _____

[List all reasonably foreseeable risks or discomforts to the subject. Separate risks into categories such as "very likely" or "less likely but serious."]

For more information about risks, ask the researcher or contact _____.

[Reference and attach any materials relevant to specific risks to participants.]

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this research, there may or may not be direct benefit to you.

[List any direct and anticipated benefits to participants. If the experimental design involves randomization, discuss anticipated benefits in terms of that.]

We hope the information learned from this research will benefit _____ (Describe population pool or others who may benefit.)

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this research study, you have these options: _____

[List alternatives including commonly used treatments or techniques.]

[If appropriate (for non-investigational treatments):]

You may get _____ (OTHER ITEMS RELATED TO STUDY PROCEDURES AT THIS FACILITY AND OTHER FACILITIES) even if you do not take part in the study.

Please talk to your regular _____ (Professional) about these and other options.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to keep your personal information confidential. *[Provide a description of how confidentiality will be maintained.]*

We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

[If appropriate:] Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as: *[List relevant agencies such as study sponsors, funding agencies, etc.]*

WHAT ARE THE COSTS?

[If appropriate:] Taking part in this study may lead to added costs to you. _____ (DESCRIBE ALL ADDITIONAL COSTS.)

You will receive (NO) payment (CREDIT) for taking part in this study. _____ (DESCRIBE ANY REMUNERATION OR INCENTIVES.)

[If the level of risk is more than minimal:] I understand that should emergency medical care become necessary during my actual participation in research activities that: (1) the research staff will make every effort to contact the Rescue Squad or appropriate emergency medical services if necessary; (2) I will be responsible for the cost of such care, either personally or through my medical insurance or other form of medical coverage; (3) no compensation for injuries which may occur as a result of this project will be paid to me by the State University of New York at New Paltz.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose not to take part, may leave the study at any time, or not answer research questions, which you consider inappropriate. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your welfare or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher(s),

_____ at _____
Name(s) Phone

For questions about your rights as a research participant, contact the State University of New York at New Paltz Institutional Review Board (which is a group of people who review the research to protect your rights) at 845-257-3282.

OTHER INFORMATION:

The Institutional Review Board of the State University of New York at New Paltz has determined that this research meets the criteria for human subjects according to Federal guidelines. - You will get a copy of this form.

CONSENT:

I have read or have had read to me the preceding information describing the study. All my questions have been answered to my satisfaction and this form is being signed voluntarily by me indicating my desire to participate in this study. I am not waiving any of my legal rights by signing this form. I understand I will receive a copy of this consent form.

Printed Name of Participant	Signature of Participant	Date
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PERMISSION:

I am the parent/legal guardian of _____ and I voluntarily approve of his/her participation.

Printed Name of Parent/Guardian	Signature of Parent/Guardian	Date
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Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date
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