

Informed Consent for a Minor to Participate in Research

Note: Most of the black text in this document can be kept as is. Modify and replace the red text to fit your study. The additional notes in blue (labeled "Note") are tips. Be sure to remove notes before submitting. Remember to proofread and format properly.

Title or paraphrased title of the study

(If applicable, designate sub-group after study title, e.g., "13–17 Year Olds")

My name is _____. I am a student/professor in the Department/College of _____ at Regis University. I am doing a research study (or if student: I am working with my teacher, Professor _____, on a research study). I'd like to tell you about this study and ask if you will take part (be a "subject") in it.

Note: Be sure to select the correct sentence – are you a professor or a student

What is a research study?

A research study is when people like me collect a lot of information about a certain thing to find out more about it. Before you decide if you want to be in this study, it's important for you to understand why we're doing the research and what's involved.

So please read this form carefully. You can discuss it with your parents or anyone else. If you have any questions about the research, just ask me.

Why are we doing this study?

Give brief explanation of why study is being done and explain study purpose in simple terms suitable for this age range.

I (and the other researchers on my team) are doing this study to find out more about _____

Why are we talking to you about this study?

Give brief explanation of why the individual is being asked to participate in study,

Note: Sample text, adjust for your particular study

To learn about _____, we would like to study _____ in people around your age. (We will do this by comparing some tests of people who have _____ with tests of people who don't. We're inviting you to participate because you are _____ or you have _____).

What will happen if you are in this study?

List all study procedures/ tests/ activities in chronological order, using bulleted format. Indicate location where procedures will take place (e.g., lab, home, or other setting), and amount of time needed for each procedure. Also note total amount of time required for study participation. See below for examples of various procedures.

If you agree to be in the study and your parents give permission, we will ask you to:

Note: Sample study procedures. Select one that best suits the needs of your study.

- Answer questions

On the first day, you and your parents will come to our lab. We will ask you and your parents to answer some questions about the way you think, act, and feel about things.

If you don't want to answer any of the questions, you don't have to.

This part will take about ___ minutes/hours.

- Do tests/ puzzles/ computer games

Then we will ask you to (briefly describe study procedures/activities, e.g.) take some tests/ solve some puzzles/ play some computer games.

Sometimes you will have to make decisions about these words or pictures on the computer. Or you will have to answer questions with a pencil and paper, or by speaking out loud. We will explain exactly what you need to do and when to do it.

You can take breaks during the tests and computer games as often as you need to.

This part will take about ___ minutes/hours.

Will you get healthier if you are in the study?

Explain possible benefits of the study, both direct/individual (if there are no direct benefits, make this clear) and indirect/general benefits to society or scientific knowledge)

Note: Sample text, adjust for your particular study

This isn't a study about getting healthier or a treatment to make you better. But we hope to learn more about _____, so in the future we can help people/other children who have _____.

Will any part of the study be uncomfortable or hurt?

List possible risks/discomforts, using bulleted format.

- *****
- *****
- *****

Who will know about your study participation?

Besides you and your parents (insert others, if applicable), the researchers are the only ones who will know about your study participation. If we publish reports or give talks about this research, we will only discuss group results. We will not use your name or any other personal information that would identify you.

To help protect confidentiality, (explain security measures to be taken for data, samples, recordings, etc. in simple terms, e.g. :) we will give your study data a code number, and keep it in a file with a password that only the researchers know. The file will be on a computer that only the researchers are allowed to use.

(If data/records will be destroyed, state when; if they will be retained, explain for how long and why, e.g. :) We plan to keep this information for ___ years, in case we or other researchers want to use it

later for other studies. But we will follow the same steps we just described to keep it as confidential as possible.

Will you get paid for being in the study?

(If no payment) You will not be paid for being in this study. (Or if payment) Your parents (or, depending on the arrangements,) You will receive (e.g., amount of money, gift cards with their value) as a thank-you for your time and effort to take part in this study. (Briefly explain how/ when compensation will be dispersed, etc.)

Do you have to be in the study?

No, you don't. Research is something you do only if you want to. No one will get mad at you if you don't want to be in the study. And remember, you can always change your mind later if you decide you don't want to be in the study any more.

Do you have any questions?

You can ask questions about this study at any time, now or later. You can talk to me, or your parents, or someone else at any time during the study. You can contact me, **PI or student investigator's name**, at **000-000-0000** or **email@xxxx.xxx**.

If you have any questions or concerns about your rights and treatment as a research subject, you can contact The Regis University Institutional Review board (IRB), which is concerned with the protection of volunteers in research projects at 303-458-4188 or by email at IRB@regis.edu.

If you decide to participate, and your parents agree, we'll give you a copy of this form to keep for future reference.

If you would like to be in this research study, please sign your name on the line below.

Subject's Name/Signature (written by adolescent)

Date

Signature of Investigator/Person Obtaining Assent

Date