Informed Consent Template

This informed consent template has been adopted by the Regis IRB to assist researchers in developing easy-to-read consent documents. The format may be expanded, but the consent form must contain all the elements below. The brackets [ ] contain additional instructions and areas for customizing the form according to the purpose and procedure of your study.

For studies involving **adult participants** (ages 18 and older), you must obtain **written** **informed consent**. If your study involves **participants ages 7-17**, you must obtain **written assent from the child and written informed consent from a parent or legal guardian**. For participants ages **6 or younger**, you must obtain **oral assent from the child** and **written informed consent from a parent or legal guardian**.

Consent cannot truly be called “informed” unless the participant understands the terms of his or her participation in the study. It is the researcher’s responsibility to ensure that the consent documents are comprehensible to the participants. **The Regis IRB requires researchers to assess the readability of their forms using the Flesch-Kincaid Grade Level score** which is calculated based on the average sentence length and the average number of syllables per word. A grade of 7.0 would indicate that a seventh grader would likely understand the document. **The Regis IRB also requires that an informed consent document for an adult (age 18 or over) not exceed a score of 7.0.** To test your document’s grade level score in Microsoft Word:

* Click the “File” tab, and then click “Options.”
* Click “Proofing.”
* Under “When correcting spelling and grammar in Word” make sure the “Check grammar with spelling” box is selected.
* Select “Show readability statistics.”

After you enable this feature, check the document’s spelling (Click the “Review” tab; click “Spelling & Grammar”). When Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

If the score is too high, try the following:

* Minimize the use of colons, semicolons, and punctuation other than standard periods and question marks.
* Use short, concise sentences. Long, complex sentences can often be divided into shorter ones to reduce the readability level.
* Use a thesaurus to find synonyms that are more comprehensible to the participants.
* People are often unfamiliar with terms commonly used in academic fields. Use lay terms, and avoid academic jargon.
* Write as if you are speaking directly with a person.

Sometimes, this process can be a bit frustrating. Try to remember that appropriate readability is at the core of fully informing research participants about their rights and what they will experience. In other words, informed consent is a vital element in conducting ethical research.

# Regis College [school or department name]

# Informed Consent to be in [title of study]

# Researcher: [name of principal investigator (PI)]

## Introduction

Please read this form carefully. You are being asked to be in a research study of [Insert a general statement about the study.]. You were selected to be in this study because [List inclusion criteria.]. You are not eligible to participate if [List exclusion criteria.]. Please ask any questions you may have before you agree to be in the study. You will receive copy of this consent form.

## Purpose of the Study

The purpose of this study is [Explain the research question and purpose in lay language.].

## What Will Happen in the Study

If you agree to be in this study, we would ask you to [Explain procedures and tasks. Identify any procedures that are experimental. Describe the length of time for participation, frequency, and duration of procedures, etc. For example, if participants will be interviewed during the study you would describe: how many interviews, the length of each interview, and/or where the interview will take place.].

## Benefits of Being in this Study

The benefits of being in this study are [State the anticipated benefits the research will produce for society and/or the participants. If there are no expected benefits, state as such.].

## Risks and Discomforts of Being in this Study

The study has the following risks. First [Explain the first risk, its likelihood, and how it will be minimized.]. Second, [Explain the second risk, its likelihood, and how it will be minimized.]. Third, . . . [If there are no foreseeable risks, state there are no expected risks.].

## Payments

You will receive the following payment for being in the study: [Explain the amount of payment or other reimbursement information (e.g., class points, tokens, donations, etc.), as well as when payment and/or reimbursement will occur and in what cases payment will not occur, if any].

[If there is no payment, state: There is no payment for being in this study.]

## Cost

There is no cost to you for being in this research study.

## Choosing to Be in the Study and Choosing to Quit the Study

It is your choice to be in this study. If you choose not to be in this study, it will not affect your current or future relations with Regis. You are free to decline to answer questions or quit at any time, for any reason. There is no penalty for not taking part or for quitting. [If you are using students, you must include a statement that participating or not participating in the study will have no impact on their academic status. If you are using employees, you must state that participating or not participating in the study will have no impact on their employment status. Explain consequences (e.g., adjusted monetary benefits) of early withdrawal, if any.]

## Getting Dismissed from the Study

The researcher may dismiss you from the study at any time for the following reasons: [Include the reasons, for example, “(1) it is in your best interests (e.g., side effects or distress), (2) you have not followed the study rules, or (3) the study sponsor decided to end the study.”].

## Privacy

The records of this study will be kept private. [Explain how information about the participants will be protected, for example, “Research records will be kept in a locked file” or “All electronic information will be coded and secured using a password-protected file.” Explain who will have access to the study records, and when and how they will be destroyed. Responses are anonymous when the researcher does not know the identity or any identifying information about who wrote them. If you are keeping a list connecting participants’ names to ID numbers, explain how you will keep that information protected and separate from your data analysis. If applicable, state that the responses are meant to be combined with other participants’ data and are not meant to gather information about specific individuals.] No published reports will include any information that will make it possible to identify you.

## Contacts and Questions

The researcher conducting this study is: [PI’s name]. The researcher will be available to answer any questions about the study at: [phone number and email address]. If you have questions or concerns about your rights, you may contact the Regis Institutional Review Board Chair:

**Dr. Margaret Oot-Hayes, PhD, RN**

**781-768-7163**

**margaret.oot-hayes@regiscollege.edu**

Statement of Consent[Choose only one statement according to the type of consent form.]

[Adult Participant Informed Consent]

I have read this form (or have had it read to me). I have been encouraged to ask questions. I have received answers to my questions. I give my consent to be in this study. I have received (or will receive) a copy of this form. I understand the risks and discomforts associated with the above study and understand that I may quit the study at any time without penalty.

[Parent/Guardian Informed Consent for Participants Ages 17 and Younger]

I have read this form (or have had it read to me). I have been encouraged to ask questions. I have received answers to my questions. I give my consent for my child to be in this study. I have received (or will receive) a copy of this form. I understand the risks and discomforts associated with the above study and understand that my child may quit the study at any time without penalty.

Signature(s)/Date[Delete any that do not apply to your protocol.]

[Adult Participant Informed Consent]

Participant Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

[Parent/Guardian Informed Consent for Participants Ages 17 and Younger]

Study Participant Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

[Interpreter for Non-English-Speaking Participants]

Interpreter Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Interpreter Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

[Participant’s Legal Representative]

Participant Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legal Representative Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legal Representative Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Witness Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_