**Informed Consent Template Directions**

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 of 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 their participation in the study. It is the researcher’s responsibility to ensure that the consent documents are comprehensible to the participants. **The Regis IRB recommends that the reading level of the informed consent document should be no higher than an 8th grade level.  The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to an 8th grade reading level. The comprehension level of the consent document must be verified to ensure it is consistent with the comprehension level of the participants. Please use the Flesch-Kincaid Grade Level score to verify the comprehension level.** 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 wider range of participants.
* Use simple, common terms, and avoid academic jargon, as people are often unfamiliar with terms commonly used in academic fields.
* Write as if you are speaking directly to 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 Participate in [title of study]**

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

**Introduction**

Please read this form carefully. You are being asked to participate in a research study of [Insert a general statement about the study]. You were selected to participate 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 participate in the study.

**Purpose of the Study**

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

**Description of Study Details**

If you agree to participate 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. Also, please provide the questions being asked].

**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 that there are no risks beyond what the participant experiences in daily life].

To the extent the study requires or involves physical interaction with other people or otherwise occurs within space shared with other individuals there is a risk of transmission of and/or infection by communicable disease including, but not limited to, the 2019 Novel Coronavirus (COVID-19). The study will be conducted in compliance with local, state, and federal guidance related to COVID-19, but despite these efforts the risks of transmission and/or infection cannot be completely eliminated.

**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 participate in the Study and Choosing to Quit the Study**

It is your choice to participate in this study. If you choose not to participate 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. This study is [Select one: anonymous, confidential, or open]. [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. Colleen C. Malachowski, PhD**

**781-768-7373**

**colleen.malachowski@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 participate in this study. 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 participate in this study. 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.

**If applicable to your study:**

I agree to be audio and/or video recorded (Check One):

\_\_\_\_\_Yes \_\_\_\_\_No

**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: \_\_\_\_\_\_\_\_\_\_