**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 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 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 7th 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 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)]**

*Your informed consent should contain the following page first (example information is used from a previously approved study at Regis – please update this to make it your own!):*

**Key Information**

The following is a short summary of this study to help you decide whether or not to participate in this study. More detailed information is listed later in this form.

***Why am I being invited to take part in this research study?***

We invite you to take part in this research study because you:

\* self-identify as a woman;

\* have graduated from a CPED-influenced EdD program within the past 3 years;

\* have had at least one child under the age of 18 in the timeframe of beginning and

completing your EdD program; and

\* have worked full-time for the entire duration of your EdD program.

You are not eligible to participate if you:

\* do not self-identify as a woman;

\* did not graduate from a CPED-influenced EdD program within the past three years;

\* have not had at least one child under the age of 18 in the timeframe of beginning and completing your EdD program; and

\* have not worked full-time for the entire duration of your EdD program.

***What should I know about a research study?***

* Whether or not you take part is up to you.
* Your participation is completely voluntary.
* You can choose not to take part.
* You can agree to take part and later change your mind.
* Your decision will not be held against you.
* Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
* You can ask all the questions you want before you decide.
* If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals in your place of employment or education.

***Why is this research being done?***

We are conducting this study to identify and understand what strategies women have employed to manage multiple roles as a mother, working professional, and student in order to persist to graduation with an EdD.

***How long will the research last and what will I need to do?***

If you agree to participate in this study, we would ask you to participate in one interview (either face-to-face or via Zoom teleconference) lasting 45 minutes to an hour. Face-to-face interviews will take place at a mutually agreed upon location and may include the participant’s work office, the researcher’s work office, or a private room in a public library. The interview would be audio recorded. If the interview is conducted via teleconference, the interview will only be recorded using an audio recorder; the interview will not be videotaped.

More detailed information about the study procedures and questions being asked can be found under ***“*Description of Study Details*”.***

***Is there any way being in this study could be harmful to me?***

This study poses minimal risks to participants. One potential but unlikely risk is that you may experience interview or focus group fatigue. In the event that you become fatigued during the interview or focus group, you may opt out of the study at any time.

More detailed information about the risks can be found under ***“*Risks and Discomforts*”.***

***Will being in this study help me in any way?***

There are no benefits to you directly from your taking part in this research. However, what we learn from conducting this study may help other working mothers in EdD programs.

***What happens if I do not want to participate in this research?***

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.

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