

[Note to investigators: This template is structured to encompass all of the possible things that you need to meet the standards for informed consent set forth in Federal law. Many of these sections can be deleted. The text is intended to be instructional, rather than declarative. Please be sure to delete all instructive text, including this paragraph, prior to submission to the IRB. Text in red font alerts investigators to complete a research specific information. Examples of sample wording are italicized. Text in bold font shows questions to be completed.]

**Background**

**Study Title:**

**Principal Investigator(s):**

**Student Researcher(s) [if applicable]:**

**IRB Study Number:**

**Introduction**

**You are invited to participate in a research study conducted by** [PI name(s)], **a** [title] **in** [the Department Name] **at Regis University. The purpose of this research is to** [describe the purpose of the study in lay terms]. **Your participation is entirely voluntary.**

**This form includes detailed information on this research study to help you decide whether to participate or not. Please read it carefully and ask any questions you have before you agree to participate.**

**Procedures**

**Your participation will involve** [Note to investigators: give a detailed description of what participants will be asked to do, taking care to use easily understandable terms. Ensure that you include a task-by-task and total time estimate. Identify if any procedures are experimental. *(e.g. “you will participate in three separate surveys which should each take 15 minutes. Your total participation in this project is expected to be 45 minutes”)*].

**If you agree to participate, the researchers will also collect** [Note to investigators: Discuss any data about the participant that you will gather that you are not receiving directly from them, as well as the source *(e.g. “collect information about your ACT scores, high school GPA, college major, and completed courses from the Registrar’s Office at your institution”).*

**Researchers will** [maintain/destroy] **the identifiable data once you agree to enter the full study.**

[Note to investigators: If you collected screening information prior to obtaining informed consent, please include this paragraph, indicating what you will do with that data*.* Choose options 1 or 2.](1) *you responded to some questions regarding eligibility description*] OR *(2) we collected information from third party/system regarding your eligibility for this study, including list information you collected here.*

**Potential Risks or Discomforts**

[Note for investigators: Explain any foreseeable risks to participants here which may include physical, psyche, reputation, employability, insurability, social status, criminal or civil liability. Keep in mind that risks are not always immediate – anger, emotional upset, or stress may appear later.

One possible option for minimal risk studies:] *Your participation in this study does not involve any physical or emotional risk to you beyond that of everyday life.*

OR

*Your participation in this study may involve the following risks*

*Examples:*

• *You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you wish to take a break or stop the interview.*

*• You may be uncomfortable with some of the questions and topics we will ask about. If you are uncomfortable, you are free to not answer or to skip to the next question.*

 *A debriefing process will take place at the end of the experiment.*

[Note to investigators: If the nature of the research is experimental and you believe it carries unforeseeable risks, please add this phrase: *This research may involve risks that are not yet known*.], you should state whether compensation and/or medical treatment is available if there is an injury and where to go or who to contact for compensation/treatment].

**We will take steps to maintain confidentiality of the information we collect from you as discussed in more detail below in the confidentiality section.**

**Possible benefits**

**Taking part in this research study may not benefit you personally. But, we may learn new things that will help others in the future.**

OR

**The possible benefits to you from this study include [**list possible benefits].

[Note to investigators: Do NOT include information on payment/reimbursement in the description of benefits – that information belongs in a separate Financial Information section. If physical injury or mental health risks are present, add a sentence stating whether and the extent to which the research-related injuries will receive treatment from the research team or from the research team’s resources.

**Confidentiality**

**The researchers will make every effort to ensure that the information you provide as part of this research remains confidential. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study.**

[Note to investigators: If you are doing research in a group setting, please add a statement that*:* *While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.]*

**We will collect your information through** [video recordings, audio recordings, interviews, Qualtrics, email… whatever mechanism(s) you are using to collect it, including indirect ones like seeking the information from a third party]. **This information or data will be securely stored** [in a restricted-access folder, and may be encrypted, in a cloud-based storage system [and/or] in a locked drawer in a restricted-access office *is Regis’s recommendation for all physical content, but please state how you’re storing/protecting things regardless of the recommendations above*]. Note to investigatorsIf you have data where identifiers can be separated and destroyed, please state the timeframe for doing so. If your data is necessarily identifying (e.g. videos, extensive demographic data, etc.) please state the timeframe for destruction of that data and what, if anything, will be kept*.* **This form will be kept for a minimum of** three **yearsafterthe study is complete, and then it** [may/will] **be destroyed.**

**It is unlikely, but possible, that others (Regis University, or State or Federal officials) may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.**

*[Note to investigators:* If you are working with any vulnerable population that carries reporting requirements, please add a statement that *If the researchers learn that you are* [abusing/neglecting/going to engage in self harm/intend to harm another], *State law requires that the researchers report this* [behavior/intention] *to the authorities.*]

**Financial Information**

*Participation in this study will involve no cost to you. You will not be paid for participating in this study.*

OR

[*Note to investigators* If subjects will be paid, explain the amount and terms of payment/reimbursement. If payments will be prorated if a subject withdraws from the study, explain the conditions for payment]

**Note to participant: If you have received compensation from research studies that in total equals $600 or more in one calendar year it must be reported to the IRS as taxable income. You will need to provide the researchers your address and Social Security number for IRS reporting purposes.**

**What are my rights as a research participant?**

**Participation in this study is voluntary. You do not have to answer any question you do not want to answer. You may choose not to participate or to withdraw from this research at any time without penalty. If you decide not to participate or to withdraw from this study, please inform the researchers. The researchers may ask you if the information already collected from you can be included in the research project.**

 [*Note to investigators* state that any information collected from the participant will not be used if the participant decides to withdraw before finishing the study. If the research participant is a Regis student or employee, include the following sentence:]

*This will not affect your class standing, grades, employment, or any other aspects of your relationship with the Regis.*

**Who can I contact if I have questions or concerns about this research study?**

**If you have questions, you are free to ask them now. If you have questions later, you may contact the researchers at** [*Note to investigators* add your contact information, including name, telephone number, and email address].

**If you have any questions about your rights as a participant in this research, you can contact the following office at the Regis University:**

**Regis Institutional Review Board**

**Regis University**

**Denver, CO 80221**

**Phone: (303) 458-4188**

**Email:** **irb@regis.edu**

**Informed Consent**

**By signing below, you agree to participate in this study. You indicate that you understand the risks and benefits of participation, and know what you will be asked to do. You also agree that you have asked any questions you might have, and are clear on how to stop your participation in the study if you choose to do so. Please be sure to retain a copy of this form for your records.**

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*Participant’s Name (printed)*

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*Participant’s Signature Date*

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*Investigator’s Name (printed)*

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*Investigator’s Signature Date*

[Note to investigators:

*You MUST provide the participants with a written copy of the informed consent document (or document oral consent) unless you have requested a waiver or alteration that permits otherwise.]*

**\*\* Optional Study Elements \*\***

[*Note to investigators***:** This section should include other explicit consents for optional elements of the research procedures, such as contacting participants again in the future about participation in other research studies, or audio/video/photographic recordings.]

*Example:*

***Consent for use of contact information to be contacted about participation in other studies***

*Initial one of the following to indicate your choice:*

*­­­­\_\_\_\_\_\_ (initial) I agree to allow the researchers to use my contact information collected during this study to contact me about participating in future research studies.*

*\_\_\_\_\_\_ (initial) I do not agree to allow the researchers to use my contact information collected during this study to contact me about participating in future research studies.*

[Note to investigators Omit the section below if you are not using video or photographic recordings].

*I agree to the session being video recorded and photographs taken.*

*\_\_\_\_\_ YES \_\_\_\_\_ NO*

*I agree to let clips from the video and photographs be used for teaching purposes, presentations or publications of the study results. My face will be blackened out in all images or video clips used and no personal information will be used to identify me.*

*\_\_\_\_\_ YES \_\_\_\_\_ NO*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Participant’s Name (printed)*

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*Participant’s Signature Date*