Baylor University

**[Department name(s)]**

Consent Form for Research

PROTOCOL TITLE: title should match protocol

PRINCIPAL INVESTIGATOR: Enter name

SUPPORTED BY: List all sources of monetary/non-monetary support. If none, list Baylor University

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| **INSTRUCTIONS:**  **READ ALL INSTRUCTIONS CAREFULLY!** This template is only part of the informed consent process. Many sections of this document include instructions **highlighted in gray** and needed language **highlighted in yellow** to provide investigators with a general overview of information required in the section. All instructions must be deleted. All information in **yellow highlighting** should be replaced with your protocol-specific information and remove the yellow highlighting. Please note that not all of the information in this form will apply to your study. Delete any information that does not apply to your study and add any information that applies to your study but is not included in this template. This is only a template and should be used as a guide. The Principal Investigator is responsible for ensuring that the study details are included in the consent form.**Delete all shaded instruction boxes and delete all gray highlighting prior to submitting this form to the IRB.** **Instructions for all consent forms:*** If using multiple consent forms – indicate differences in title (e.g., students, teachers, parents, children ages 7-12, adolescents 12-17, focus group, interviews, experiment or intervention, group A, group B, etc.)
* Write in lay language understandable to the participant population. Aim for an 8th grade or lower reading level.
* Minimize the use of academic/scientific terminology and jargon; define or describe the meaning of terms.
* Spell out the meaning of all acronyms at their first use.
* Refer to the participant in the second person (e.g., you, your).
* Use at least a 12 pt. font. Certain populations (e.g., elderly, young children, etc.) may require a larger font to improve readability.
* Include a version date in the footer on every page. Each time the consent is revised, this version date must be updated.
* DO NOT ADJUST THE MARGINS OF THE TEMPLATE.
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**Purpose of the research:** The purpose of this study is to briefly explain the purpose of the study. We are asking you to take part in this study because specify reason for recruiting this individual.

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| **INSTRUCTIONS:** Provide a list of all study activities and when they will occur. Common activities for exempt research are:* Give you some questionnaires to fill out about your physical health, mood, mental and emotional health, quality of life, and habits
* Ask about your medical and mental history
* Ask about your medications
* Interview you about your experiences with…
* Take part in a focus group. A focus group is a small group of people who take part in a discussion about a selected topic. The focus group will be led by a member of the research staff. The focus group leader will ask the group members about their opinion of …
* Ask you to complete tasks on the computer.

If subjects will be audio or video recorded, include this information.If subjects will be randomized to different groups, include this information. |

**Study activities:** If you choose to be in the study, you will state what the subject is being asked to do, preferably in bulleted format. Long, wordy paragraphs are hard to read.

**Risks and Benefits:**

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| **INSTRUCTIONS:** The information in this section should be limited to the risks and discomforts **related** to the procedures done for research purposes, and should not include those related to a research subject’s routine care, unless it would aid the subject’s understanding of the study. Describe the reasonably foreseeable risks and discomforts of each study procedure. Include physical, psychological, social, and legal risks. **Even if the risk or discomfort seems minor, it must be disclosed if it is reasonably foreseeable.**Below are some common risks and discomforts for exempt research. **Customize this section according to your protocol.** OVPR is happy to provide or help you create risk language for this section. |

No foreseeable risks

To the best of our knowledge, there are no risks to you for taking part in this study.

Risks of Completing Tasks

You may get tired during the tasks. You can rest at any time.

Interviews

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

Questionnaire/Survey Risks

You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.

Psychological Testing/Sensitive Topics

This research study involves psychological testing. The questions being asked may be sensitive and personal in nature. It is possible that answering some questions may cause some stress. Insert options for subject if they should feel uncomfortable providing a response or become distressed, e.g., they can skip any questions, they will be referred for counseling, etc.

Focus Groups

The researchers will ask you and the other people in the group to use only first names/pseudonyms during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

Incomplete Disclosure

As part of this research, you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be given an explanation of what information was withheld from you at the end of your study participation.

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| **INSTRUCTIONS:** The first sentence should indicate that the participant may **not** benefit from taking part in this research study. **Do not include payment as a benefit.** Include the following information in this section:* Possible benefits to the subject (if any).
* Benefits to others in the future
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If no benefits

There are no benefits to you from taking part in this research.

If possible benefits

You may or may not benefit from taking part in this study. Possible benefits include state benefit.

If future benefit

Others may benefit in the future from the information that is learned in this study.

For studies awarding course credit/extra credit for participation

You do not have to take part in this research study to receive course credit. Your alternative for equal credit is state alternative for credit.

**Confidentiality:**

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| **INSTRUCTIONS:** Information on plans to protect data from unplanned disclosure is required for all consent forms. Choose the appropriate language below. Language concerning the reporting of possible abuse or harm should only be included if the research is likely to elicit such information and the individual will be identifiable. |

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The researcher plans to protect your confidentiality.

If internet-based research

Confidentiality will be maintained to the degree permitted by the technology used. Your participation in this online survey involves risks similar to a person’s everyday use of the Internet, which could include illegal interception of the data by another party. If you are concerned about your data security, contact the researcher to schedule a time to complete a printed survey with the same questions/you should not participate in this research.

We will keep the records of this study confidential by state how you will ensure that the subject’s records are kept confidential**.** We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

Authorized staff of Baylor University may review the study records for purposes such as quality control or safety.

Delete the below language if you aren’t likely to obtain information concerning these issues.

By law, researchers must release certain information to the appropriate authorities if they have reasonable cause to believe any of the following:

* Abuse or neglect of a child
* Abuse, neglect, or exploitation of an elderly person or disabled adult
* Risk of harming yourself or others
* Alleged incidents of sexual harassment, sexual assault, dating violence, or stalking, committed by or against a person enrolled at or employed by Baylor University at the time of the incident

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| **INSTRUCTIONS:** If you will be sending study information to researchers outside of Baylor University, add this information. |

We will send your study information to research collaborators at outside site. State how confidentiality will be maintained.

**Compensation:**

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| **INSTRUCTIONS:** Include the following information in this section:* Provide specific information about payment (money or other forms of compensation or reimbursement, e.g., gift certificate, meal voucher, parking voucher, and travel expenses)
* Include how the amount of compensation is calculated if the subject does not complete the entire study for any reason, e.g., “If you do not complete all of the study visits, we will give you $25 for each study visit you completed.”
* State when subjects will be paid (e.g. after each visit or after study is completed, etc.)
* For lottery/raffle drawings, include the following: when the drawing will occur, who will conduct the drawing, how payment will be made, the value of the prize, the number of prizes, and the chances of winning.

**Note: If participants will not be paid or will not receive other forms of compensation for participation, delete this section.****See sample statements below.** |

If you will reimburse some or all expenses

We will pay for your parking/transportation/other while you are taking part in this study.

If a single payment

We will pay you state amount/method of compensationfor completing the survey/interview/focus group/etc.

If more than a single payment

We will pay you state amountfor each visit/task that you complete. You will be paid with check/cash/gift card/etc. If you complete all the study visits/tasks, we will pay you a total of state amount**.** If you do not complete the entire study, we will pay you for each visit/task that you complete.

If providing course or extra credit

We will give you state amount of course creditfor taking part in this study.

If lottery or raffle

We will enter your name into a drawing for state prize**.** With number of subjects taking part in the study, your chances of winning are state chance, e.g. 1 in 500**.** The drawing will be conducted by state personafter all subjects have completed the study which will be on or about, date. You will be contacted only if your name is drawn.

**Questions or concerns about this research study**

You can call us with any concerns or questions about the research. Our telephone numbers are listed below: List contact information for PI and/or other applicable study staff. State the hours that study staff can be contacted. If you are a student, include the contact information for your Faculty Advisor.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), you may contact the Baylor University IRB through the Office of the Vice Provost for Research at 254-710-3708 or irb@baylor.edu.

Taking part in this study is your choice. You are free not to take part or to stop at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. Information already collected about you cannot be deleted.

By continuing with the research and completing the study activities, you are providing consent.