Baylor University

**[(Department name(s)]**

Consent Form for Research

PROTOCOL TITLE: **(title should match protocol and grant)**

PRINCIPAL INVESTIGATOR:

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

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| **INSTRUCTIONS:**  This template is only part of the informed consent process. Many sections of this document include brief instructions and wording suggestions **in bold font** to provide investigators with a general overview of information required in the section. The instructions/information in **bold font** should be replaced with your protocol-specific information.  Please note that not all of the information in this form will apply to your study. Please delete any sections that do 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.  **Please delete all shaded instruction boxes prior to submitting this form to the IRB.** |

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| **INSTRUCTIONS:** Include the following paragraph only if some or all of the adult subjects are incapable of providing consent and permission for their participation will be obtained from their authorized representative. Delete the following paragraph when all subjects are adults capable of providing consent. |

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of a medical or other condition. Instead we will ask the person’s legally authorized representative (LAR) to give consent. Throughout the consent form, “you” always refers to the person who takes part in the study.

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| **INSTRUCTIONS:** Include the following paragraph only when **some** of the subjects are minors (less than 18 years of age) and permission for their participation will be obtained from their parent(s)/guardian (i.e., the study includes both adults and minors). Delete the following paragraph when **all** subjects are adults.  **Note**: For studies that are limited to minors, instead of using this consent form, prepare a Permission Form for Parents and an Assent Form for Minors. |

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) or guardian to give permission for them to take part in the study, and we will ask the minor to agree (give their assent) to take part. Throughout the consent form, “you” always refers to the person who takes part in the study.

**Introduction**

Please read this form carefully. The purpose of this form is to provide you with important information about taking part in a research study. If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Taking part in this research study is up to you. If you decide to take part in this research study we will ask you to sign this form. We will give you a copy of the signed form.

The person in charge of this study is **[Insert name of PI. If student, also include faculty advisor name].** We will refer to this person as the “researcher” throughout this form.

**Why is this study being done?**

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 you **are/have [Specify reason for recruitment.]**

About **total number** of subjects will take part in this research study at Baylor University.

**How long will I take part in this research study?**

We expect that you will be in this research study for **total study time**. During this time, we will ask you to make **number** study visits to **location (e.g. Psychology clinic at Baylor University)**

**What will happen if I take part in this research study?**

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| **INSTRUCTIONS:** Provide a list of all study procedures/tests/activities and when they will occur. Include the following information:   * The length and duration of visits and procedures. * Which procedures are being performed as standard of care and which are part of the research study, when applicable. Do not include procedures that would occur regardless of the subject’s participation unless it would aid the subject’s understanding of the study. * Information about the study design, e.g., randomization * Special requirements, e.g., stopping current medications, fasting before tests * Reasons and procedures for early withdrawal from the study * Sending data/specimens to research collaborators * Storage of data/specimens for future use   Study-related procedures should be chronological (such as by visit). You can also list all study procedures and then include a chart indicating at which visit(s) the procedure will occur. |

If you agree to take part in this study, we will ask you to sign the consent form before we do any study procedures.

**Study Visit 1**

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| **INSTRUCTIONS:** Below is a list of common possible procedures. Customize this list for your study. Use the format below for all subsequent study visits (Visit 2, Visit 3, etc.) |

Visit 1 will take about **how long** to complete. At this visit, we will ask you to do the following procedures:

* 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
* Measure your vital signs (blood pressure, temperature, heart and breathing rates)
* Give you an ECG (electrocardiogram). This test checks the electrical activity of your heart. We will place several, small, sticky pads on your chest, arms, and legs. There is a wire attached to each pad. The wires connect to a machine that makes a recording of your heart rhythm.
* Interview you about your experiences with **describe subject.**
* 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 **topic.**
* Give you an MRI (magnetic resonance imaging) of your **body location**. A MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. During the MRI, we will ask you to lie still on a table that slides into a tunnel-shaped machine. The machine is slightly wider than your body. The top and sides of the tunnel will be very close to your body. The MRI machine makes loud noises as it take pictures of the insides of your body. We will give you earplugs to reduce the noise. You will be able to hear and speak to the research staff at all times during the MRI procedures. We can stop the procedure at any time, if necessary. The MRI will take about **amount of time.**
* Ask you to complete tasks on the computer
* Give you an EEG (electroencephalogram). An EEG is a test that measures and records the electrical activity of your brain. We will put special sensors (electrodes) on your head. There is a wire attached to each sensor. The wires connect to a computer. The computer records your brain's electrical activity on the screen or on paper as wavy lines.
* Give you a DXA (or DEXA) scan. A DXA is a type of x-ray used to measure bone strength. During this test, X-ray pictures of your body will measure how much fat and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of the body. This test will last about **amount of time**.

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| **INSTRUCTIONS:** If subjects will be randomized to different study arms or groups, include the information below. |

We will assign you by chance (like a coin toss) to one of two study groups. One group will **describe group (e.g., will receive brochures on lifestyle changes)** and the other group **describe group (e.g. will receive brochures on lifestyle changes and also meet with a counselor)**. You and the researcher cannot choose your study group. You will have an **equal chance/ 2 out of 2 chance, etc.** of being assigned to either study group.

**Audio/Video Recording**

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| **INSTRUCTIONS:** If subjects will be audio or video taped, add the following information. Choose the appropriate language depending on whether audio or video taping will be done. Include information about how the tapes will be used and how long they will be stored. Choose the correct language concerning whether it is optional or not. |

We would like make **a/an** **audio/video** recording of you during this study. If you are recorded it **will/will not** be possible to identify you on the recording. We will store these recordings in a locked cabinet and only approved study staff will be able to access them. We will label these recordings with a code instead of your name. The key to the code connects your name to the recording. The researcher will keep the key to the code in a **password-protected computer/locked file. State how long recordings will be stored.**

**Audio/video** recordingis **required/optional** for this study**. (If required)** If you do not want to be recorded, you should not be in this study. **(If optional)** If you do not want to be recorded, you can still be in the study. You will indicate your decision at the end of this form.

**What are the risks of taking part in this research study?**

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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 reasonable foreseeable risks, side effects, and discomforts of each study procedure, drug/supplements, device, etc. Include physical, psychological, social, and legal risks. Risks of drugs/supplements should be listed in bullet format with the most common or likely first.  Below are some common risks and discomforts. 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, taking part in this study will not hurt you.

**Drug/Placebo/Supplement/Device**

**Blood Draw Risks**

Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn.

**MRI Risks**

There are no known harmful effects from the strong magnetic field used for MRI. But the magnet is very powerful. The magnet may affect pacemakers, artificial limbs, and other medical devices that contain iron. The magnet will stop a watch that is close to the magnet. Any loose metal object has the risk of causing damage or injury if it gets pulled toward the strong magnet. Before you have the MRI, we will ask you about any metal within your body (this includes certain dyes in tattoos). You will need to remove all metal objects (such as hearing aids, dentures, jewelry, watches, and hairpins) from your body because these objects may be attracted to the powerful magnet used for the test.

You should not have an MRI if you have claustrophobia (fear of small spaces). The top and sides of the machine will be very close to your body. Because of this, you may feel anxious while inside the MRI machine. If you do feel anxious during the procedure, you can ask us to stop the MRI at any time.

If you are pregnant or suspect you are pregnant, you should inform the study staff before the MRI examination. Although there is no known risk of using MRI in pregnant women, the safety of MRI during pregnancy has not been established. Therefore, you cannot have an MRI for this study if you are pregnant or think that you are pregnant.

**Risks from Radiation**

Procedures such as DXA scans, CT scans, and/or X-rays will be used during this research study. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect you **or your disease**. However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease. When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

**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.

**Deception**

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.

**Loss of Confidentiality**

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. Their plans for keeping your information private are described later in this consent form.

**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, please contact the researcher to schedule a time to complete a printed survey with the same questions.

**Pregnancy/Breastfeeding Risks**

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| **INSTRUCTIONS:** Include this section if it is possible that any test articles, procedures, or tests in the study may involve risks to an embryo or fetus if the subject is or may become pregnant. |

Taking part in this study while you are pregnant could cause harm to your fetus. If you are breastfeeding, taking part in this study could cause harm to your baby. You must not take part in this study if you are pregnant or breastfeeding. If you are a sexually active woman of childbearing age and would like to take part in this study, talk with the researcher about ways to avoid pregnancy. If you think that you have become pregnant while taking part in this study, you must contact the researcher right away.

**If applicable, include the following:** There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

**Incidental Findings**

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| **INSTRUCTIONS:** Include the section below if it is anticipated that any procedures or tests in the study may reveal an incidental finding. Incidental findings are apparent medical abnormalities that may have clinical implications and are observed in the course of research studies but are unrelated to the topic under study. Examples might include:   * A study involving fractionation of normal human blood suggests a potential infection; * A baseline study of mental status indicates a psychiatric condition; * A screening for an exercise intervention identifies a cardiac insufficiency; * A brain imaging study of depressed individuals reveals a potential structural abnormality |

Although the **procedure(s)/test(s)** you will have in this study **is/are** being undertaken for research purposes only, it is possible that researchers may notice something that could be important to your health. If so, we will contact you to explain what was noticed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

**Are there any benefits from being in this research study?**

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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 |

**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.

**What alternatives are available?**

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| **INSTRUCTIONS:** List any alternatives. If there is no alternative to participation, the statement below is sufficient. |

You may choose not to take part in this research study.

**For studies awarding course 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**

**If subjects are also patients:** You do not have to take part in this research study to be treated for **medical condition being studied.** Other treatments available for your condition include: **state other available treatments**

**Storing Study Information for Future Use**

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| **INSTRUCTIONS:** If you would like to store data for future research, include the information below. Chose the correct language concerning whether it is optional or not. |

We would like to store your study information for future research related to **condition/topic (e.g., depression, memory, learning, etc.)**. We will label all your study information with a code instead of your name. The key to the code connects your name to your study information. The researcher will keep the code in a **password-protected computer/locked file.**

Future use of study informationis **required/optional** for this study**. (If required)** If you do not want your information to be used for future research, you should not be in this study. **(If optional)** If you do not want your information to be used for future research, you can still be in the study. You will indicate your decision at the end of this form.

**Storing Samples and Health Information for Future Use**

We would like to store some of your samples and health information for future research related to **general disease area or condition**. We will label your samples and health information with a code instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a **password protected computer/locked file**.

Your samples will be stored at **location**. Your sample will be kept for **enter years or indefinitely**. **(If not indefinitely)** After that time, the sample will be destroyed by methods in accordance with laboratory or institution procedures.

Future use of samples and health informationis **required/optional** for this study**. (If required)** If you do not want your samples and health information to be used for future research, you should not be in this study. **(If optional)** If you do not want your samples and health information to be used for future research, you can still be in the study. You will indicate your decision at the end of this form. If you agree to the storage of your samples now, but change your mind in the future, contact the researcher to request destruction.

**Sending Study Information to Research Collaborators Outside Baylor University**

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

We will send your study information to research collaborators at **outside site**. We will label all your study information with a code instead of your name. The key to the code connects your name to the study information. The researcher will keep the key to the code here at Baylor University and will not share it with our research collaborators. Nobody outside of Baylor University will know which study information is yours.

**How Will You Keep My Study Records Confidential?**

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.

**Reporting child/elder abuse, if applicable:** If, during your participation in this study, we have reasonable cause to believe that **child/elder** abuse is occurring, this will be reported to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court will demand the release of identifiable research information.

**Reporting risk of harm to self or others:** If, during your participation in this study, we have reason to believe that you are at risk for harming yourself or others, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

The following people or groups may review your study records for purposes such as quality control or safety:

* The Researcher and any member of **his/her** research team
* Authorized members of Baylor University who may need to see your information, such as administrative staff members from the Office of the Vice Provost for Research and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)
* The sponsor or funding agency for this study
* Federal and state agencies that oversee or review research (such as the HHS Office of Human Research Protection or the Food and Drug Administration)

The study data will be stored **state where data will be stored.**

The results of this study may also be used for teaching, publications, or presentations at professional meetings. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

**If Certificate of Confidentiality is Obtained:** We have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS) for this study. This certificate adds special protection for research information that identifies you. This Certificate does not mean that the government approves or disapproves of this study.

With this Certificate, we cannot be forced (for example by court order or subpoena) to release any identifying research information about you. You should understand that the Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research study. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate does not prevent the researchers from voluntarily disclosing, without your consent, information that would identify you as a subject in this research study if we: 1) are concerned that you may be suicidal (thinking about killing yourself) or at immediate risk of seriously harming yourself or others, or 2) learn about serious harm to you or someone else (such as child abuse or elder abuse). Under these circumstances we will notify the appropriate people (such as your personal doctor, counselor, local or state agency, or other authorities).

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| **INSTRUCTIONS:** Include the following paragraph if the study will be registered on clinicaltrials.gov to meet FDAAA clinical trials registration requirements. This requirement applies to certain clinical trials of drugs (including biological products) and medical devices. This paragraph must be included even if the sponsor is the responsible party for clinical trials registration. This paragraph is not required when registering only to meet journal requirements. For guidance, go to www.clinicaltrials.gov.  The below paragraph **cannot** be edited. |

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include any information that can identify you. At most, the Web site will include a summary of the results of this research. You can search this Web site at any time.

**Study Participation and Early Withdrawal**

Taking part in this study is your choice. You are free not to take part or to withdraw 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. You cannot withdraw information collected prior to your withdrawal.

**If students are enrolled:** You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or your grades at Baylor University. You will not be offered or receive any special consideration if you take part in this research study.

**If Baylor faculty or employees are enrolled:** You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your job status at Baylor University. You will not be offered or receive any special consideration if you take part in this research study.

**If the researcher can withdraw the subject:** The researcher may take you out of this study without your permission. This may happen because:

* The researcher thinks it is in your best interest
* You can’t make the required study visits
* Other administrative reasons

**If a drug/supplement/device study:** For your safety, you should tell us if you want to stop being in the study. You may be asked to give back any **study drug/supplement** that you have not used **and/or** come back for a final visit.

**Will I get paid for taking part in this research study?**

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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, please state.**  **See sample statements below.** |

You will not be paid for taking part in this study.

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

We will pay you **state amount** for each visit/task that you complete. 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.

We will give you **state amount of course credit** for taking part in this study.

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 person** after all subjects have completed the study which will be on or about, **date.** The study staff will contact you if your name is drawn.

**What will it cost me to take part in this research study?**

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| **INSTRUCTIONS:** The following information is provided to help you prepare this section of your consent form. Include the appropriate statements in this section and delete the rest. You may add further language to describe specific items/services/amounts that will be the subject’s responsibility. |

**If no costs:** There are no costs to you for taking part in this research study.

**If study will pay for test articles**: Study funds will pay for the (**enter** **study drug/supplement/placebo or device)** that **is/are** used in this research.

**If study will pay for procedures:** Study funds will pay for the **(enter procedures/tests such as** **MRI/DXA/blood draws)** that **is/are** done for research.

**If subject will be receiving standard medical care/therapy while taking part in the study:**

If you are receiving medical treatment as part of your routine clinical care while taking part in this research study, your routine clinical care will be billed to you/your insurance company in the usual way.

**What happens if I am injured as a result of participating in this research study?**

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| **INSTRUCTIONS:** This section can be deleted if there is no more than minimal risk to subjects, unless there are medical procedures being performed (such as blood draws or imaging). |

If you become ill or injured as a result of your participation in the study, you should seek medical treatment from your doctor or treatment center of choice. You should promptly tell the researcher about any illness or injury.

There are no plans for Baylor University to pay you or give you other compensation for your injury or illness. You do not give up any of your legal rights to seek compensation by signing this form.

**What if I have any 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 want to speak with someone **not** directly involved in this research study, you may contact the Baylor University IRB through the Office of the Vice Provost for Research at 254-710-1438. You can talk to them about:

* Your rights as a research subject
* Your concerns about the research
* A complaint about the research

**Indicate your decision for the below optional research discussed earlier in this form:**

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| **INSTRUCTIONS:** If there are any optional decisions for the subject to make, add appropriate language and choices. Common decisions are listed below. |

**Optional Consent for Audio/Video recording:**

Do you agree to let us make **a/an** **audio/video** recording of you during this study?

\_\_\_\_\_\_YES \_\_\_\_\_\_NO \_\_\_\_\_\_\_INITIALS

**Optional Consent for future research with study information:**

Do you agree to let us store your study information for future research related to **condition/topic**?

\_\_\_\_\_\_YES \_\_\_\_\_\_NO \_\_\_\_\_\_\_INITIALS

**Optional Consent for future research with samples and health information:**

Do you agree to let us store your samples and health information for future research related to **general disease area or condition**?

\_\_\_\_\_\_YES \_\_\_\_\_\_NO \_\_\_\_\_\_\_INITIALS

**Future Contact**

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| **INSTRUCTIONS:** If you want to contact the subject in the future for follow-up questions or to recruit for future studies, add the language below. |

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Baylor University.

Do you agree to let us contact you in the future?

\_\_\_\_\_\_YES \_\_\_\_\_\_NO \_\_\_\_\_\_\_INITIALS

**Statement of Consent**

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| **INSTRUCTIONS:** Include signature line(s) as appropriate to the subject population and consent process described in the protocol documents. Delete those signature lines that are not applicable. If you are requesting a waiver of documentation of consent, delete all signature lines. If consent is being obtained via the internet, insert language such as “By clicking “I Agree” you are providing consent to be in the study.” |

**SIGNATURE OF SUBJECT:**

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| **INSTRUCTIONS:** Include the following signature line when informed consent and authorization for participation of some or all subjects will be obtained directly from the subjects. |

I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

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Signature of Subject Date

**SIGNATURE OF PARENT(S)/GUARDIAN FOR CHILD:**

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| **INSTRUCTIONS:** Include the following signature line when informed consent and authorization for participation of some or all child subjects will be obtained from parents/guardian. |

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

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Signature of Parent/Guardian Date

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Signature of Parent/Guardian Date

## Signature of Legally Authorized Representative for Adult:

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| **INSTRUCTIONS:** Include the following signature line when informed consent and authorization for participation of some or all adult subjects will be obtained from a guardian, health care proxy, durable power of attorney, or family member/next-of-kin (I.e., an LAR). Include signature line(s) for decisionally-impaired adult subjects as appropriate to the subject population and assent process described in the protocol documents. Delete the assent signature lines if not applicable. |

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below)

Court-appointed Guardian

Health Care Proxy

Durable Power of Attorney

Family Member/Next-of-Kin. Relationship: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Signature of Legally Authorized Representative Date

Assent of Adult Subject Requiring an LAR:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

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

Signature of Adult Subject Date

## Witness to Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

|  |
| --- |
| **INSTRUCTIONS:** Include the following signature line when you anticipate enrolling adult subjects who cannot read or write in any language or subjects who are physically unable to talk or write. |

### Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent for participation by (check one box as applicable):

Making his/her mark above

Other means \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(fill in above)

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

Signature of Witness Date

**Signature of Person Obtaining Consent:**

|  |
| --- |
| **INSTRUCTIONS:** Always include the section below for written consent. |

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

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

Signature of Person Obtaining Consent Date