Baylor University

**[Department name(s)]**

Consent Form for Research

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

PRINCIPAL INVESTIGATOR: **[name]**

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

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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 unbolded 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.  Additionally, you can use **IRB-CK-03: IRB Informed Consent Checklist** to help create your consent form. Use the **IRB-G-07: Standard Consent Language** guidance for already approved IRB language.  **Please delete all green-shaded instruction boxes prior to submitting this form to the IRB.** |

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| **Invitation to be Part of a Research Study** |

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

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| **Important Information about this Research Study** |

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| **INSTRUCTIONS:** For research studies that will require more than a 3-page consent document, provide a concise and focused presentation of key information that is most likely to help potential subjects understand the full scope of the study to determine whether or not to participate. Organize and simplify information to facilitate comprehension.  **Delete this section if not necessary for the study.** |

Things you should know:

* The purpose of the study is to **[briefly describe study purpose]**.
* In order to participate, you must be **[briefly describe basic eligibility criteria].**
* If you choose to participate, you will be asked to **[do what, when, where, and how]**. This will take **[state period of time]**.
* Risks or discomforts from this research include **[briefly describe most likely risks or state that the risks involved in this study are not greater than everyday life]**.
* The possible benefits of this study include **[provide a description of potential benefits to subjects or state that there is no direct benefit for participating in this study]**.
* Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form. Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

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| **Why is this study being done?** |

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| **INSTRUCTIONS:** If you have used the summary above, provide additional details in this section. |

The purpose of this study is to **[describe the purpose of the study].**

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

If you agree to take part in this study, you will be asked to **[provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)]**.

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| **INSTRUCTIONS:** Include in this section a full and complete description of the study procedures explained from the participant’s perspective. After reading this section, the participant should have a good understanding of what they will experience and be asked to do. It is recommended that bullet points are used to facilitate comprehension and clarity. Example:  • [Task One]: [Description of task], [Amount of Time]  • [Task Two]: [Description of task], [Amount of Time]  Use lay language to facilitate the participant’s understanding. DO NOT copy technical language from the IRB application, sponsor protocol or a grant.  If study activities occur over many days and would be communicated more clearly chronologically revise the bullet points to describe each day or consider using a table format.  If the study involves the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas.  Include only information about the research activities in this study, not activities that would be done for usual care or other purposes (e.g., normal education, standard clinical care, quality improvement) regardless of participation in the study. Explain what aspects of usual care will be altered or omitted because of this study as applicable.  As appropriate, and particularly for complex studies or studies with multiple visits, include study calendars or other tables, figures, or graphics to assist the subject in understanding what will be asked of them.  **If subjects will be audio or video recorded:** If subjects will be audio or video taped, add the following information:  We would like to make **a/an** **audio/video** recording of you during this study. **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. |

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

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| **How long will I be in this study and how many people will be in the study?** |

Participation in this study will last **[describe how long total participation will last]**. About [**total number]** of subjects will take part in this research study.

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

There are some risks you might experience from being in this study. They are **[describe specific risks]**. **[OR]** We don’t believe there are any risks from participating in this research.

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| **INSTRUCTIONS:** Include in this section a full and complete description of all reasonably foreseeable risks and discomforts the participants might experience. 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.  **Use lay language** (the non-technical meaning), rather than a medical/academic term (ex: use “weakness” instead of “asthenia”).  Describe the reasonable foreseeable risks, side effects, and discomforts of each study procedure, drug/supplement, 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.  Many studies at Baylor involve the use of similar instruments, measures, devices, etc. The ORC maintains a library of standard/sample language that conveys these risks to participants. See the **IRB-G-07: Standard Consent Language** guidance located on the Guidance Page for sample language and definitions.  **If the research presents more than minimal risk to the participant, include the following statement:** This study may involve risks that are currently unforeseeable. |

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

You might benefit from being in this study because **[insert details]**.

**[OR]**

Although you will not directly benefit from being in this study, others might benefit because **[insert details]**.

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| **What if you learn something about my health that I did not know?** |

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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.

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| **How Will You Protect my Information?** |

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.

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.

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

* The sponsor or funding agency for this study **[delete if there is no sponsor]**
* Representatives of Baylor University and the BU Institutional Review Board
* Other collaborating organizations **[list other organizations or delete if not applicable]**
* Federal and state agencies that oversee or review research (such as the HHS Office of Human Research Protection or the Food and Drug Administration)
* **[If research is conducted in foreign countries include the following:]** This research is also being conducted in foreign countries, so personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

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| **INSTRUCTIONS:** If biospecimens are collected and whole genome sequencing will (if known) or might occur, insert the following:  Research using your specimens may include mapping your DNA (whole genome sequencing). This information could identify you. Ask the study team if you have questions. |

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.

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| **INSTRUCTIONS:** If your project is NIH-funded and collects identifiable, sensitive information, it will be covered by a Certificate of Confidentiality (CoC) –**OR**– if you will apply for a CoC for non-NIH-sponsored research collecting health-related, identifiable, sensitive information, insert the language found in **IRB-G-07: Standard Consent Language**. |

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| **INSTRUCTIONS:** Include the following language if it is likely that, in the course of the research, information concerning any of the following could be obtained:  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:** All applicable clinical trials must be registered on clinicaltrials.gov. The following language is required for clinical trials:  A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. |

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| **Will information and/or biospecimens you collect about me be used for future research studies?** |

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| **INSTRUCTIONS: Choose one of the following statements to include in this section.**  Information and/or biospecimens collected from you as part of this research will not be used or distributed for future research studies, even if the identifiers are removed.  **OR**  Information and/or biospecimens collected from you as part of this research may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before the information and/or biospecimens are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from what is shared. |

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| **Will I be compensated for being part of the 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.**  **Sample statements:**  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.  **If total payment or tangible item value is over $100, add the following:**  Per University Policy, to pay you we will need to collect your social security number or Individual Taxpayer Identification Number for tax purposes. If you do not want to provide this information, you can still be in the research study, but we cannot pay you. |

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| **Are there any costs to me to be part of the study?** |

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| **INSTRUCTIONS:** Delete this section if not applicable. |

To participate in the research, you will need to pay for **[list what costs subjects will have to pay (such as parking, lab tests, etc.)]**.

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| **What happens if I am hurt by 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.

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| **Who can profit from study results?** |

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| **INSTRUCTIONS:** Include this section only if a conflict of interest has been identified or if biospecimens are collected. Delete this section if not applicable to the study.  Where a potential Conflict of Interest (COI) for a member of the study team has been identified, subjects must be informed about the nature of the conflict. Examples include:   * Investigators have an ownership, consulting, or similar financial relationship with a sponsor. * A company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study whose product is being studied, particularly if the company/organization is also the sponsor of the study or has a financial interest with the investigators. * Baylor University may be paid licensing fees for the investigational technology, or could be paid in the future. Contact the Office of Technology Commercialization if you are uncertain.   See sample language in **IRB-G-07: Standard Consent Language**. Additionally, the BU COI review committee may require language to be included in the consent documents.  **If collecting/obtaining biospecimens, one of the following must be included:**  Option 1:  Your samples may be used for commercial profit and there is no plan to share those profits with you.  Option 2:  Your samples may be used for commercial profit and there are plans to share those profits with you. [Explain profit sharing plan]  Option 3:  Your samples will not be used for commercial profit. |

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| **What other choices do I have if I do not take part in this study?** |

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| **INSTRUCTIONS:** List any alternatives. If there is no alternative to participation, delete this section.  **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].  **For studies that involve an intervention that might treat or improve a condition or a disease:** 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] |

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| **Is it possible that I will be asked to leave the study?** |

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| **INSTRUCTIONS:** Delete this section if not applicable to the study. |

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

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| **Your Participation in this Study is Voluntary** |

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 you are a Baylor student or faculty/staff member, 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 grades or job status at Baylor University. You will not be offered or receive any special consideration if you take part in this research study.

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| **Contact Information for the Study Team and Questions about the Research** |

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| **INSTRUCTIONS:** List who can be contacted – PI is required and an alternative contact is encouraged.  **For International Studies:** List the name, email and phone of the local collaborator, if any, first. Be sure to include the U.S. calling code and exit number for the country of origin. The number will be in the following format: Phone: XXX+1-734-936-0933.  **If you are a student**, include the contact information for your Faculty Advisor. |

If you have any questions about this research, you may contact:

[Name of PI]

Phone:

Email:

Or

[Name of secondary contact person(s)]

Phone:

Email:

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| **Contact Information for Questions about Your Rights as a Research Participant** |

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), please contact the following:

Baylor University Institutional Review Board

Office of the Vice Provost for Research

Phone: 254-710-3708

Email: [irb@baylor.edu](mailto:irb@baylor.edu)

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| **INSTRUCTIONS for International Studies**: List information for the local IRB or Ethics Committee, if any, first. Omit the BU IRB phone number. Instead, include the U.S. calling code and exit number for the country of origin. The number will be in the following format:  Phone: XXX+1-254-710-3708. |

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| **Your 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. |

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree to take part in this 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 assent of the child and parental permission will be obtained from parents/guardian with a single consent form. |

By signing this document, you are agreeing to your child’s participation in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for my child to take part in this study.*

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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. Otherwise, delete this section. |

By signing this document, you are agreeing to the person’s named below participation in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for the person named below to take part in this study.*

Print Name (check applicable box below)

Court-appointed Guardian

Health Care Proxy

Durable Power of Attorney

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

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

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Signature of Legally Authorized Representative Date

Assent of Adult Subject Requiring an LAR:

*I understand what the study is about and my questions so far have been answered. I agree to take part in this study.*

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Signature of Adult Subject Date

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

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| **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. Otherwise, delete. |

### 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)

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Signature of Witness Date

**Signature of Person Obtaining Consent:**

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| **INSTRUCTIONS:** Only include this signature line when the project is required to adhere to GCP requirements. Otherwise, delete. |

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.

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Signature of Person Obtaining Consent Date

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| **Optional Research** |

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| **INSTRUCTIONS:** You may also need to obtain consent for specific activities when those activities are ***optional***. Whether an activity is required or optional must be clearly described in the main body of the consent above. Some common optional research activities are included below:  **Consent to be Audio/video Recorded**  I agree to be audio/video recorded.  YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_ Initials \_\_\_\_\_\_\_\_  **Consent to Use Data for Future Research**  I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information. *(Note: This separate consent is not necessary if you will only store and share deidentified data.)*  YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_ Initials \_\_\_\_\_\_\_\_  **Consent to be Contacted for Participation in Future Research**  I give the researchers permission to keep my contact information and to contact me for future research projects.  YES\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_ Initials \_\_\_\_\_\_\_\_ |