# Please submit one document (Word or PDF) with all of the questions answered and appendices for any surveys, CITI training certificates, or other relevant files. Be sure to cite your appendices in the appropriate section(s) of the document.

# HUMAN SUBJECT PROTECTION

Houston Christian University respects the rights and welfare of individuals recruited for or participating in research conducted by or under the auspices of the University. All research involving human subjects is reviewed and approved by the Institutional Review Board prior to initiation and subsequently by continuing review and monitoring of approved studies. In the review and conduct of research, actions by the University will be guided by the ethical principles of autonomy, beneficence, and justice set forth in the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (often referred to as the Belmont Report) and will be performed in compliance with the Department of Health and Human Services (HHS) policy and regulations at 45 CFR 46 (also known as the “Common Rule”). The actions of the University will also conform to all other applicable federal, state, and local laws and regulations.

# INSTITUTIONAL REVIEW BOARD

To conduct its responsibility effectively, HCU maintains a committee to review research protocols involving human subjects. The Institutional Review Board (IRB) has been established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University. The IRB has the following authority:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the University;
2. To suspend or terminate approval of research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants;
3. To observe or have a third party observe the consent process; and
4. To observe or have a third party observe the conduct of the research.

All IRB approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB.

The IRB has jurisdiction over all human subject research, regardless of funding source. This includes research conducted at HCU, conducted by or under the direction of any employee or agent of HCU (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of HCU using any property or facility of this institution, or involving the use of HCU's non-public information to identify or contact human subjects.

Appropriate officials at the University (the President, Provost, or General Counsel) may review any research protocol and have the right to disapprove the implementation of a research protocol that has been approved by the IRB. However, no one at the University shall approve the implementation of any research protocol or override the decision of the IRB concerning a research protocol that has been disapproved by the IRB.

Please visit [www.hc.edu/irb](http://www.hc.edu/irb) for more information.

**CATEGORIES OF REVIEW FOR RESEARCH PROTOCOLS**

The IRB uses specific regulatory definitions and refers to the human subject’s protections regulations in determining the appropriate level of review. Examples provided below are intended only to guide an investigator's determination of the level of review needed. Please contact the IRB with any questions.

## 1. NO REVIEW NEEDED

Only research is reviewed by the IRB. A study does not require review if it is NOT a systematic investigation that will contribute to generalizable knowledge. No IRB forms are to be completed. Regardless of the need for review, the faculty member/ investigator is responsible for ensuring that all human subjects are protected.

## 2. EXEMPT FROM REVIEW

A study is exempt from review if it meets criteria relating to normal educational practices and maintains subject privacy. Determinations that a research project is exempt from review are made by the IRB. Exemption from review is only available to certain categories of research, as defined by federal regulation:

1. Anonymous survey and interview procedures or observation (without intervention) of public behavior.
2. Survey and interviews to which the identity of the participant can be linked but the information obtained is innocuous. Disclosure of this information would NOT reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
3. If information is recorded without any identifiers, study of **existing** data or pathological specimens.

### Application Procedure

*Complete the* [*Approval Request and Consent Form*](#_APPROVAL_REQUEST_AND) *and include rationale for the requested exemption.* Provide an abstract of the proposed research in language that can be understood by a layperson. The abstract should summarize the objectives of this project, the procedures to be used, the study population, the nature of the data to be obtained, and how participant privacy will be protected or confidentiality of the data will be maintained.

### IRB Response

Upon receipt of an application for an exempt determination, the IRB will review the application and respond with questions and clarification requests, and will notify the investigator by letter of the exemption.

## 3. EXPEDITED REVIEW

This level of review only applies to research involving no more than minimal risk. Minimal risk is defined as a risk level similar to what is encountered in daily life or during performance of routine physical or psychological exams or tests. Only certain categories of research activities, as defined by federal regulation, are eligible for expedited review. NOTE: The standards of review for expedited studies are the same as for studies that receive Full Committee review.

Examples of research eligible for expedited review:

1. Surveys, interviews, and focus groups which can be linked to individual participants and request some types of "sensitive" information.
2. Blood draws.
3. Study of data collected for non-research purposes, for example study of clinical data or pathological specimens.
4. Collection of data or specimens using non-invasive procedures including audio, video, EEG, and ECG recordings, and ultrasound and MRI imaging.

### Application Procedure

*Complete the* [*Approval Request and Consent Form*](#_APPROVAL_REQUEST_AND) *and include rationale for an expedited review.*

### IRB Response

Upon receipt of a completed application and associated materials, the IRB will review materials and respond with questions and clarification requests, and will notify the investigator in writing of approval/disapproval. Continuing review (renewal) is required for studies receiving expedited review.

**4. FULL COMMITTEE REVIEW**

1. Criteria for exempt or expedited review are not met.
2. Invasive medical treatments.
3. Physical, psychological, economic, reputational, or social risk involved.
4. Special populations (minors, prisoners, participants lacking decision making capacity).

**Application Procedure**

*Complete the* [*Approval Request and Consent Form*](#_APPROVAL_REQUEST_AND)*.*

### IRB Response

Upon receipt of a completed application and associated materials, the IRB will review materials and respond with questions and clarification requests, and will notify the investigator in writing of approval/disapproval.

Continuing review (renewal) is required for studies receiving full committee review.

**INSTITUTIONAL REVIEW BOARD**

# APPROVAL REQUEST AND CONSENT FORM

The following format is to be used in submitting proposals to the Institutional Review Board (IRB) at [irb@hbu.edu](mailto:irb@hbu.edu). The faculty member in charge of the research project must be the one to email the completed application to [irb@hbu.edu](mailto:irb@hbu.edu). Please use the following template and respond to each of the questions, creating an electronic file that can be emailed to [irb@hbu.edu](mailto:irb@hbu.edu).

If you believe that your proposal may be exempt from review by this committee, you must still submit the following information and any required accompanying materials to the chair of this committee.

1. Name, address, and phone number for student researcher.
2. Name and title of faculty research mentor (principal investigator).
3. If applicable, names for all Dissertation or Thesis Committee Members
4. Program of study for the proposal
5. Department of origin of the proposal
6. Title of proposal and date of submission
7. Research proposal abstract (maximum of 250 words)
8. Are you receiving funds to support this project? If YES, please indicate the source or sources of funding.
9. Number of subjects required
10. Type of subjects (e.g., college students, K-12 educators, minors)
11. Source of subjects (e.g., subject pool, particular classes, professional societies)
12. Please respond to each of the following questions:
    1. Who will be the subjects and how will they be recruited?
    2. Describe the psychological and/or physiological stimuli or interventions and the means used to administer these stimuli or interventions. Indicate the steps that will be taken to assure the proper operation of the equipment used to administer stimuli. Give particular attention to prevention of accidental harm or injury to the subjects.
    3. Describe the level of risk to which the subjects will be exposed by participating in this study. If the proposed research exposes the participants to any level of risk, attach a detailed description and justification for the risk.
    4. Is there any deception of the subjects that will be involved? If so, what is its rationale, its necessity, and why is the research so important as to justify its use? Are there modifications to this research that would allow for genuine informed consent?
    5. Describe the expected behavior of the subjects and the behavior of the investigator during the study. This must include a written statement of what is to be read to, or said to the subject concerning the study.
    6. Describe how the subjects are to be debriefed and the mechanism for alleviation of stress or psychological harm that may derive from participation in this study.
    7. How will you ensure compliance to HCU’s data storage policy ([www.hc.edu/irb](http://www.hc.edu/irb))?

All data used for either publicly published graduate theses or dissertations must be turned in to the Center for Research and Doctoral Studies (CRDS) at the time of uploading the thesis to ProQuest. This data will be kept by the CRDS for no more than five years. The purpose of this storage is to make sure there is a record of the research in case any questions are raised regarding it. If you are writing a publicly published graduate theses or dissertations then one of your three storage locations will be the CRDS.

Identify the three locations specified in terms of location and format, taking into account whether or not CRDS must be one of those locations. Identify who will have access to the three forms of the data. Identify what the data will be used for and that it will be stored for at least two years in each of the three locations.

* 1. If the current project is being conducted by students, describe the level of involvement of the faculty advisor.

1. Describe how the subjects’ privacy and anonymity will be protected.
2. Describe how this research address HCU’s initiative, including the “Ten Pillars 2030” (<https://hc.edu/about-hbu/ten-pillars/> ).
3. In accordance with Federal regulations, University policy on research involving human subjects requires the use of “informed consent forms”, which must be signed by the subject or the legally authorized representative of the subject. One copy of the appropriate, completed form(s) must accompany the proposal to the Institutional Review Board. If the study involves children, a copy of the letter or other communication to parents providing the essentials of the proposed study must also accompany the proposal to the Institutional Review Board.

The Informed Consent form is on the next page and should be filled in according to the proposed research project.

1. Include a copy of any questionnaires or interview questions that will be used. Include the actual questions, not a web link.
2. Attach the CITI training certificates for all researchers associated with the research project.

**All proposals must be signed by the student investigator and faculty research mentor. A digital signature is sufficient.**

“I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. I will take personal responsibility for the safekeeping of all raw data (e.g., test protocols, tapes, questionnaires, interview notes, etc.) in a college office or computer file.”

Signature of Faculty Research Mentor\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Student Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Houston Christian University**

**[Department name(s)]**

Consent to Take Part in a Human Research Study

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

PRINCIPAL INVESTIGATOR: **[name]**

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

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| Per the Common Rule, the Research Team is responsible for including prospective research subjects with a concise summary of the information related to the research study such that a reasonable person can make an informed decision about whether or not to participate in the study.  **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.  **Please delete all blue-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 information presented in 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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| **Why is this study being done?** |

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.  **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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| **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. Please state your three sources based on the HCU data storage policy].** 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 Houston Christian University and the HCU 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.

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:** 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 Houston Christian University at the time of the incident |

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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?** |

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

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| **What happens if I am hurt by participating in this research study?** |

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.

Houston Christian University reserves all its rights under law and equity.

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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). |

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

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| **INSTRUCTIONS:** Include this section only if a conflict of interest exists. 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. |

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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?** |

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

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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 Houston Christian University 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 Houston Christian 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** |

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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| **INSTRUCTIONS:** List who can be contacted – PI is required and an alternative contact is encouraged.  **If you are a student**, include the contact information for your Faculty Advisor. |

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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:

Houston Christian University Institutional Review Board

Email: irb@hbu.edu

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| **Your Consent** |

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| **INSTRUCTIONS:** Include signature line(s) as appropriate to the subject population and consent process. 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 of Research Participant (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 Good Clinical Practice (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 \_\_\_\_\_\_\_\_ |

Research Participants are encouraged to retain a copy of their signed consent form for their own records. The original signed copy should be given to the Research Group.