



INSTRUCTIONS: PLEASE EDIT THE DOCUMENT TO MATCH THE SCOPE OF YOUR PROPOSED STUDY. IF A SECTION IS NOT APPLICABLE TO YOUR PROPOSAL SCOPE, REMOVE AND/OR EDIT THIS DOCUMENT ACCORDINGLY. EVALUATIONS OF YOUR INFORMED CONSENT DOCUMENTS WILL BE BASED ON COMPLIANCE EVALUATION OF YOUR SUBMITTED APPLICATION IN THE CAYUSE APPLICATION

INFORMED CONSENT: ADULT RESEARCH PARTICIPANT

You are being asked to participate in the research project described in the procedures section below. Your participation in this study is entirely *voluntary*, and you may refuse to participate, or you may decide to stop your participation at any time. Should you refuse to participate in the study, or should you withdraw your consent and stop participating in the study, your decision will involve no penalty or loss of benefits to which you may otherwise be entitled as described in the corresponding sections below. You are being asked to read the information below carefully and ask questions about anything you don't understand before deciding whether or not to participate. If you have any questions about this study or your rights as a participant, you are encouraged to contact UHCL's Office of Research and Sponsored Programs (ORSP) at sponsoredprograms@uhcl.edu or at [281-281-3015](tel:281-281-3015).

The following focused information is being presented to assist you in understanding the key elements of this study, as well as the basic reasons why you may or may not wish to consider taking part. This section is only a summary; more detailed information, including how to contact the research team for additional information or questions, follows within the remainder of this document.

Title: *Click or tap here to enter text.*

Institutional Review Board (IRB) #: *Click or tap here to enter text.*

Research Funded by *(if applicable):*

Principal Investigator(s): *Click or tap here to enter text.*

Student Investigator(s): *Click or tap here to enter text.*

Faculty Sponsor: *Click or tap here to enter text.*

Purpose of the Study: *Click or tap here to enter text. – why is this research being done by telling the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others. Be careful not to include technical jargon; the document should be written in language understandable to the population being recruited (studies recruiting the general public should be written at no higher than an 6th grade reading level)*

Procedures: *Click or tap here to enter text.*

How many people might be included in be studied: *Click or tap here to enter text. Be sure to choose either the single site or the multi site option.*

[Multi-site study] We expect about _____ people here will be in this research study out of _____ people in the entire study nationally [or internationally].

[Single-site study] We expect to enroll about _____ people in this research study.



Expected Period Duration: Click or tap here to enter text. The *duration at which you the PI expect that you will be in this research study for _____ [hours/days/months/weeks/years, until a certain event. If more than a single visit, specify the total duration of the study and the amount of time each subject should expect to commit to the study (e.g. number of study visits and the length of time for each visit.)*

Risks of Participation: Click or tap here to enter text. Is the primary risk to you in taking part is _____ *[name most important/prevalent behavioral, biomedical, legal, economic, and/or privacy/confidentiality risks, if applicable. If not applicable, state that there are no known risks].* Instead of being in this research study, your choices may include *[List appropriate alternatives which may be advantageous or delete the statement if the only alternative is not participating]*

(FOCUS GROUPS - use below in focus group studies)

Although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of their fellow participants and not repeat what is said in the focus group to others. Please do not share anything in the focus group, you are not comfortable sharing. *(If you are collecting data using the internet and/or email, you may consider including the following)* Data will be collected using the Internet; we anticipate that your participation in this presents no greater risk than everyday use of the Internet. *Please note that email communication is neither private nor secure.* Though we are taking precautions to protect your privacy, you should be aware that information sent through email or internet could be read by a third party.

Benefits to the Subject

There is no direct benefit received from your participation in this study, but your participation will help the investigator(s) to better understand **Insert Project and/or Project name**

Confidentiality of Records

Every effort will be made to maintain the confidentiality of your participation and records. The data collected from the study will be used for educational and/or publication purposes, however, you will not be identified by name. For compliance purposes, the participant's documentation for this research project will be maintained and safeguarded by the Principal Investigator and/or Faculty Sponsor for a minimum of three years or longer after completion of the study. After that time, the participant's documentation may be destroyed.

Compensation (If applicable)

To compensate you for the time you spend in this study, you will receive _____ (describe compensation).

(State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If compensation is pro-rated over the period of the participant's involvement, indicate the points/stages at which compensation changes during the study.)

Investigator's Right to Withdraw Participant



The investigator has the right to withdraw you from this study at any time. In this case, you will be notified of your removal from this study by either the investigator and/or a member of the investigator’s team.

Contact Information for Problems and/or concerns

Please contact the Office of Research and Sponsored Programs (ORSP) at 281-283-3015 or sponsoredprograms@uhcl.edu or researchcompliance@uhcl.edu

Contact Information for Questions

The investigator has offered to answer all of your questions. If you have additional questions during the course of this study about the research or any related problem, you may contact the Principal Investigator, **Click or tap here to enter text.** by telephone at **Click or tap here to enter text.** or by email at **Click or tap here to enter text.** Or ORSP at 281-283-3015 or sponsoredprograms@uhcl.edu

{Or, Student Researcher information}

If you have additional questions during the course of this study about the research or any related problem, you may contact the Student Researcher, **Click or tap here to enter text.** by telephone at **Click or tap here to enter text.** or by email at **Click or tap here to enter text.** The Faculty Sponsor, **Click or tap here to enter text.** may be contacted by telephone at **Click or tap here to enter text.** or email at **Click or tap here to enter text.** Please also contact our Office of Research and Sponsored programs at sponsoredprograms@uhcl.edu researchcompliance@uhcl.edu or call us at 281-283-3015.

Identifiable Private Information (if applicable)

Identifiers might be removed from identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility *OR* Information or biospecimens collected as part of the research, even if identifiers are removed, will not be used for or distributed for future studies.

Future Studies It is okay to use my data in other studies:

Please initial: _____ Yes _____ No

When the investigator is audio recording, video recording, or photographing participants, add the following:

As part of this study, it is okay to (audio record, videorecord, or photograph – include only process(es) pertinent to your study) me:

Please initial: _____ Yes _____ No



What happens if I say yes, but I change my mind later?

You can leave the research at any time, and it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research, *[Describe the adverse consequences such as only partial compensation for work completed, or for students only partial course credit.]* If you decide to leave the research, contact the investigator so that the investigator can *[Describe the procedures for orderly withdrawal by the subject, if any.]*

[Describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. Explain if their data up to the point collected, will still be used for analysis or if it will be removed from the research record.] If you stop being in the research, already collected data that still includes your name or other personal information *will be/will not be/may not be removed* from the study record.

Signatures

Your signature below acknowledges your voluntary participation in this research project. Such participation does not release the investigator(s), institution(s), sponsor(s) or granting agency(ies) from their professional and ethical responsibility to you. By signing the form, you are not waiving any of your legal rights.

The purpose of this study, procedures to be followed, and explanation of risks or benefits have been explained to you. You have been allowed to ask questions and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. You have read this form of consent and voluntarily agree to participate as a subject in this study. You are free to withdraw your consent at any time by contacting ORSP, Principal Investigator, or Student Researcher/Faculty Sponsor. You will be given a copy of this consent form you have signed.

Subject's printed name: [Click or tap here to enter text.](#)

Signature of Subject: [Click or tap here to enter text.](#)

Date: [Click or tap here to enter text.](#)

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject. ***In your application, you must describe the methodology which you will use to obtain the informed consent. Please note that even if a signature by the research participant is not obtained, the research participant(s) must be provided with a copy of this consent document.***

Printed name and title: [Click or tap here to enter text.](#)

Signature of Person Obtaining Consent: [Click or tap here to enter text.](#)

Date: [Click or tap here to enter text.](#)

THE UNIVERSITY OF HOUSTON-CLEAR LAKE (UHCL) INSTITUTIONAL REVIEW BOARD (IRB) HAS REVIEWED AND APPROVED THIS PROJECT. ANY QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH SUBJECT MAY BE ADDRESSED TO THE UHCL IRB (281-283-3015). ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT UHCL ARE GOVERNED BY REQUIREMENTS OF THE UNIVERSITY AND THE FEDERAL GOVERNMENT.
(FEDERALWIDE ASSURANCE #FWA00004068)