

Consent to Take Part in a Human Research Study

Title of research study: *[insert title of research study here (must match protocol title)]*

Investigator: *[insert name of principal investigator. If the PI is a student, indicate that project is part of thesis or dissertation being conducted under the supervision of (faculty sponsor's name).]*

Key Information:

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 under the "Detailed Information" heading.

What should I know about a research study?

- Someone will explain this research study to you.
- Taking part in the research is voluntary; whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, and can ask questions at any time during the study.

*[New Common Rule regulations require that prospective subjects be provided with a **concise summary of information (up front)** that a reasonable person would want in order to make an informed decision about whether to participate. This summary may be different based on the type of study being conducted (behavioral, biomedical, risk level) and population being recruited. We recommend the following, in a high-level, 1-2 paragraph format:]*

We invite you to take part in a research study about _____ because you meet the following criteria_____. *[Fill in the circumstance or condition that makes subjects eligible for the research.]*

[Include for sponsored research. Otherwise, delete.] This research is being funded by *[Insert name of sponsor]*.

In general, your participation in the research involves _____ *[include a high level/concise summary of the procedures that will be done and include the duration of the subject's participation. You will be able to provide a more detailed description of procedures in a section below. For example, you will be given a questionnaire about how you feel and be asked to complete it on 3 separate occasions. You will also provide a total of 3 blood samples.]*

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],* which you can compare to the possible benefit of *[List possible personal benefits, if applicable, if not, indicate that there is no personal benefit, however the possible benefit to society may be X. Do not include remuneration as a benefit].* You will *[or will not]* receive compensation for participation. *[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]*

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Detailed Information:

The following is more detailed information about this study, in addition to the information listed above.

Why is this research being done?

[Tell 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 8th grade reading level)

How long will the research last?

We 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.)*

How many people will be studied? *[Choose either multi- or single-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.

What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:

- *A timeline-style description of the procedures that will be performed. If practical, prepare a chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits*
- *The length and duration of visits and procedures*
- *With whom will the subject interact*
- *Where the research will be done*
- *When the research will be done*
- *List study procedures and what the participant will be asked to complete*
- *Which parts of the study are experimental*
- *What portions are in addition to standard care, if in a treatment setting*
- *If blood will be drawn, indicate the amount by comparing to tablespoons or teaspoons*
- *How often procedures will be performed*
- *If randomized to groups, indicate that the intervention will be chosen by chance, like the flip of a coin*
- *If surveys or interviews are conducted, indicate if sensitive subject matter is involved, and give examples of such questions. Indicate whether subjects may skip questions that may make them uncomfortable.*
- *Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen*

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[Include if any Audio, Video and/or Photography that will be included as part of the research project, otherwise delete.]

This research study includes the following component(s) where we plan to audio record/video record/photograph you as the research subject: *[list component(s) and select only the applicable modes of media]*.

- I agree to be [audio recorded/video recorded/photographed] during the research study.
 - I agree that the [audio recording/video recording)/photographs] can be used in publication/presentations.
 - I do not agree that the [audio recording/video recording)/photographs] can be used in publication/presentations.
- I do not agree to be [audio recorded/video recorded/photographed] during the research study.

[A statement must be included here to indicate if the subject may still participate if they do not agree to be audio recorded/video recorded/photographed]

[Include for a clinical trial that involves randomization. Otherwise, delete]

The treatment you get will be chosen by chance, like flipping a coin. You will have an _____ *[equal/one in three/etc.]* chance of being given each treatment. *[For placebo-controlled trials, add]* One of these treatments may contain no active treatment (such as a sugar pill), called a placebo. *[For double-blinded research, add]* Neither you nor the study doctor will know which treatment you are getting. *[For single blinded research, add]* You will not be told which treatment you are getting, however your study doctor will know.

[Include for research that involves randomization of subjects (non-clinical trials). Otherwise, delete.]

The research *[procedures/intervention]* you will receive will be chosen by chance, like flipping a coin. You will have an _____ *[equal/one in three/etc.]* chance of being given each treatment.

What are my responsibilities if I take part in this research?

[This section is required for clinical trials, and describes responsibilities of the subject such as taking study medications, keeping study appointments, etc. For non-clinical trials, it may be deleted if study procedures are clearly detailed above.]

If you take part in this research, you will be responsible to: *[Describe any responsibilities of the subject.]*

What happens if I do not want to be in this research?

You can choose not to take part in the research and it will not be held against you. Choosing not to take part will involve no penalty or loss of benefit to which you are otherwise entitled.

[Include if the research may enroll students. Otherwise, delete] If you are a student, a decision to take part or not, or to withdraw from the research will have no effect on your grades or standing with *[name the school or institution]* *[Include if the research involves clinical patients. Otherwise, delete]* If you are receiving clinical care, a decision to take part or not will have no effect on what would be offered to you as part of routine care.

[Include if there are alternatives other than participating:] Instead of being in this research study, your choices may include *[List alternative procedures. For student subject pools, describe alternatives for course/extra credit (required). For clinical trials describe the options that you would normally offer a patient. If applicable, include supportive care as an option.]*

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[Include for a clinical trial. Otherwise, delete.] The important risks and possible benefits of these alternatives include: *[Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]*

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.]* If you decide to leave the research, contact the investigator so that the investigator can *[Describe the procedures for orderly termination by the subject, if any.]*

[Include for FDA-regulated research. Otherwise, delete. If you are unsure if the research involves a drug, device, or biologic regulated by the FDA, please contact the IRB office.] If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. *[Note: The consent document cannot give the subject the option of having data removed.]* If you agree, this data will be handled the same as research data. *[Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.]*

[For research that is not FDA-regulated, 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. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

Is there any way being in this study could be bad for me?

If there are no known risks: We do not expect any risks related to the research activities. If you choose to take part and undergo a negative event you feel is related to the study, please contact [the researcher/study team](#).

[Otherwise, describe each of the following risks in detail, if appropriate. If known, describe the probability and magnitude of the risk.]

- *[Physical risks]*
- *[Psychological risks]*
- *[Privacy risks]*
- *[Legal risks]*
- *[Social risks]*
- *[Economic risks]*

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise, delete.] In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for research that involves pregnant women or women of childbearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise, delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: _____. **[Omit the previous sentence if there are no known risks.]** The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. **[Omit the previous two sentences for research whose risk profile in pregnancy is well known.]** You should not be or become

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pregnant *[include as applicable “or father a baby”]* while on this research study. *[Include whether pregnancy testing is required as part of the research]*

[Include for research that may result in additional costs to the subjects. Otherwise, delete.] Taking part in this research study may lead to added costs to you. *[Describe what these costs are. Note: If there are parking costs associated with research visits, state whether parking will be paid for/validated]*

[Include for a clinical trial. Otherwise, delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will I receive anything for being in this study?

[Describe any compensation or payment that the subject can expect to receive for their participation. For example, gift card (state type and amount), remuneration for the subject’s time/travel, ticket to the zoo, book, etc. If the remuneration is pro-rated based on the procedures/measures completed/not completed, then this must be stated. If the payment will only occur if all procedures/measures are completed, then this must be specifically stated.]

Will being in this study help me in any way?

[Include if there are benefits to participation. Do not over-promise benefits of experimental interventions]. We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include _____. *[Describe the potential benefits of participation. First, describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]*

[Include for research with no benefits to participation.] There are no known benefits to you from your taking part in this research. However, possible benefits to others include _____. *[Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]*

[Include for research involving prisoners. Otherwise, delete.] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

What happens to the information collected for the research?

[For only completely anonymous research where no identifiers (including codes) can be matched to the subject for the duration of the research, such as online surveys]: Your taking part in this project is anonymous, and information you provide cannot be linked to your identity.

[For all other research] Efforts will be made to keep your personal information private, including research study and medical records, to people who have a need to review this information. Each subject’s name will be paired with a code number, which will appear on all written study materials. The list pairing the subject’s name to the code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee our research. *[Add for sponsored research. Otherwise, delete.]* The sponsor of the research *[list]* may also review research records upon request. *[If HIPAA-regulated. Otherwise, delete.]* This research uses or discloses Protected Health Information as defined by the Health Insurance Portability and Accountability Act (HIPAA), and you will be asked to sign an additional document to authorize the use of this information.

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We may publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:

This study collects *private information with identifiers (such as name, birthdate, etc.) and/or identifiable biological specimens (samples from your body such as blood, tissue, etc.)*. Following collection, researchers may choose to remove all identifying information from these *data or samples*. Once identifiers are removed, *this information and/or these samples* could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your *information and/or biological samples* that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise, delete.] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

[Include for research involving prisoners. Otherwise, delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

[For studies being conducted under a Certificate of Confidentiality, you may either contact the IRB office for help with drafting applicable language to include in the consent form, or utilize and edit, as needed the suggested language below. NIH suggests editing the suggested consent language as necessary for your study population, for example lower literacy or non-English speakers, so long as all relevant points related to disclosure and consent are covered:

This research is covered by a Certificate of Confidentiality from the *[insert applicable agency issuing the CoC]*. The researchers with this Certificate may not share or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. *Information, documents, or biospecimens* protected by this Certificate cannot be shared with anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *[THE FUNDING AGENCY]* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug

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Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed, such as including research data in the medical record]*.

We may share and/or publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise, delete.] The person in charge of the research study or the sponsor *[remove study sponsor if not applicable]* can remove you from the research study without your approval. Possible reasons for removal include *[describe reasons why the subject may be withdrawn, if appropriate.]*

[Include for research where this is a possibility. Otherwise, delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

[Include for research involving more than minimal risk. Otherwise, delete.] If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University of Houston–Clear Lake has no program to pay for medical care for research-related injury. *[Describe any compensation available for research related injury.]*

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise, delete.] Military personnel should check with their supervisor before accepting payment for taking part in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise, delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you arrange to be followed by a physician.

[Include when applicable.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *[or replace with plans when using identifiable information/samples]* to tell you, or to pay you, or to give any compensation to you or your family.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens,] Most tests done on

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samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers *will/will not* contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you should talk to the research team at *[Insert contact information for the research team, including a UHCL email address and a phone number at UHCL that is routinely monitored.]*

[If the study takes place internationally, provide contact information for the local contact (and IRB/ethics board, if applicable)]

This research has been reviewed and approved by the University of Houston-Clear Lake Institutional Review Board (IRB). You may also talk to them at (281) 283.3015 or sponsoredprograms@uhcl.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

[Include if the study meets the definition of a clinical trial according to NIH or ICMJE requirements. Otherwise, delete.] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

May we contact you regarding future research opportunities?

[When applicable, include a checkbox asking if the subject wishes to be contacted for future research in a similar area and/or conducted by the PI's study team. Contact information should not be collected on the consent form itself. Please note that efforts to create a permanent research subject database typically require the submission of a separate IRB protocol.] In the future, our research team may be interested in contacting you for other research studies we undertake, or to conduct a follow-up study to this one. There is never any obligation to take part in additional research. Do we have permission to contact you to provide additional information?

Yes

No

[There are two signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent. Please note that for online surveys, a link to the cover letter must be provided in the application, and a checkbox must be included for the subject to click "I have read the consent information and agree to take part in the research" prior to moving forward to the study instrument(s).]

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Signature Block for Capable Adult

Your signature documents your consent to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

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Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative

Date

Printed name of legally authorized representative

Signature of person obtaining consent

Date

Printed name of person obtaining consent

[Add the following block if you will document assent of the subject.]

- Assent
- Obtained
 - Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process