## 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?

1. Someone will explain this research study to you.
2. Taking part in the research is voluntary; whether or not you take part is up to you.
3. You can choose not to take part.
4. You can agree to take part and later change your mind.
5. Your decision will not be held against you.
6. 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 are 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]

## 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:

* 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
* How often procedures will be performed

***[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]***

## 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 UH 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 the University of Houston.

[Include if there are alternatives other than participating. Otherwise delete.] Instead of being in this research study, your choices may include: [List alternative procedures. For student subject pools describe alternatives for course credit (required).

## 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.

***[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 ***will be/will not be/may not be*** removed from the study record.

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

If there are no known risks: There are no foreseeable risks related to the procedures conducted as part of this study. If you choose to take part and undergo a negative event you feel is related to the study, please inform your study team.

[Describe each of the following risks, 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 ***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.]

***Will I get 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.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then 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.]

## 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 limit the use and disclosure of your personal information, 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 assigned code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee human subjects research. [Add for sponsored research. Otherwise delete.] The sponsor of the research ***[list]*** may also review research records upon request***.***

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.

## 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.

## 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 UH email address and a phone number at UH that is routinely monitored.]

This research has been reviewed and approved by the University of Houston Institutional Review Board (IRB). You may also talk to them at (713) 743-9204 or cphs@central.uh.edu if:

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

Please note that for online surveys, a link to the cover letter must be provided in the IRB protocol, 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).]