San Diego State University

INFORMED CONSENT FORM

Consent form version date: Revise the date: a) each time changes are made to a previously approved consent form and submitted with a modification, and b) when revisions are made in response to conditions.

Note to Investigator: Informed Consent is the knowing consent of an individual or his/her legally authorized representative that is obtained without undue inducement or element of force, fraud, deceit, duress, or other forms of constraint or coercion. A consent form documents voluntary and informed consent. This document is designed to provide information to the potential subject about the research and the subject's potential involvement.

Use this format in all non-exempt research. **Red text are instructions, please delete all instructions written in red once the informed consent is complete.** The content of this consent must be written in the 2nd person and target a sixth to eighth grade reading level. Use the section headings within this template and at least an 11 -12 point font.

If the investigator is using multiple consent forms for the same study, please complete separate informed consent forms. DELETE THIS "Note to Investigator" BOX BEFORE SUBMITTING THE INFORMED CONSENT FORM TO THE vIRB.

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(Insert study title—if you are using multiple consent forms for the same study, include the study group in the title. For example for a study involving a separate consent form for parents and teachers you would title the consent forms —Study XYZ –Teacher participants and Study XYZ—Parent Participants)

If the study is conducted by a student, the Co-Investigator/Faculty Sponsor should be listed. If staff other than the investigator will consent subjects or have access to identifiable data, include their name(s) in the section below.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Principal Investigator:
SDSU Department:
Address:
Phone:
Email:

Co-Investigator/Faculty Sponsor:
SDSU Department:
Phone:
Email:

Co-Investigator:
SDSU Department
Phone:
Email:

Research Staff:
Phone:
Email:

WHAT IS THE PURPOSE OF THIS RESEARCH:

This study involves research. The purpose of this study is to…
Approximately <number> of participants will be included at San Diego State University.

If your study involves randomization, include a statement of the study treatment and the probability of random assignment to each treatment.

HOW LONG WILL I BE IN THIS RESEARCH?

Give the total amount of time a participant will be involved in the study. Include the number of study visits and the frequency of the visits if applicable. See italicized red text below for examples.

Example: Your participation will last one month. You will come to SDSU for eight (8) study visits twice per week for four (4) weeks. Each visit will last one hour.

Example: Your participation will last one hour. You will come to SDSU for one study visit lasting one hour.

WHAT WILL HAPPEN IN THIS RESEARCH?

If a screening procedure is used to determine eligibility to participate, include a description of the screening instrument. State whether the information obtained from those who are ineligible will be maintained.

For example: To determine if you are eligible to participate, you will be asked to complete a questionnaire about your health history. If your responses indicate you are eligible to participate, you will be asked to participate in the training and testing portion of this study. If you are not eligible to participate, the information obtained during the screening will not be included in the study data and the screening questionnaire will be shredded to protect your privacy.

Describe the location and the procedures in chronological order. List all procedures the participant is expected to complete for research purposes only and specify any research procedures which are experimental. If there are several procedures involved it can be helpful to include a bulleted list or a table as shown below.

	Visit 1 Day 1	*Visit 2 Day 14*	*Visit 3 Month 3*	*Visit 4 Month 6*	*Visit 5 Month 12*
Screening tests and medical history	*X*				
Blood draw (1 Tablespoon.)	*X*	*X*	*X*	*X*	*X*
Quality of Life Questionnaire	*X*			*X*	*X*
Total time	*4 hours*	*30 minutes*	*30 minutes*	*3 hours*	*3 hours*

Indicate which procedures, if any, to be conducted are experimental.

For example, a certain procedure might be experimental or a drug might be experimental. It is also possible that the only experimental aspect of the study is that all of the information is being collected for analysis. If this is the case, include the following statement: "None of the procedures [or questionnaires, if applicable] used in this study are experimental in nature. The only experimental aspect of this study is the gathering of information for the purpose of analysis."

WHAT ARE THE RISKS OR DISCOMFORTS INVOLVED IN THE RESEARCH?

DO NOT state that there are no risks associated with your study. Describe any risks posed by the research project. You must provide a description of any risks or discomforts the participant might encounter as a result of participation. Include a description of the provisions you have made to address the risks or discomforts.

See Supplement Language on the HRPP website if your research involves the following:

For Focus Group

For Survey/Interview

Blood draw

For MRI

For DNA Research

For women participants if applicable add: If you are pregnant or become pregnant the treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable.

There may be new findings developed during this research which may relate to your willingness to continue to participate in this study. These new findings will be shared with you.

ARE THERE ANY BENEFITS TO PARTICIPATION?

Note: Incentives to be paid to the study participant are not benefits to participation.

If there are possible benefits: Include a statement to describe any potential benefits that may result from this research. If there are possible benefits, list the benefits and include the following language: There is no guarantee, however, that you will receive any benefits from participation.

If there are no benefits use the following language*:* There are no benefits for participating in this research; however by participating you are you are helping to provide information which may benefit science and society.

ARE THERE ANY ALTERNATIVES TO PARTICIPATION?

An alternative is to not participate. When applicable inform participants of appropriate alternative procedures or treatment which might be available.

WILL MY INFORMATION BE PRIVATE?

Please inform the subjects about the extent to which their personally identifiable private information will be held in confidence include the following statement: Confidentiality will be maintained to the extent allowed by law. Required text for studies involving interviews, questionnaires, surveys, or other procedures during which the PI may suspect child or elder abuse. However, the study team members are required by California law to report suspected child or elder abuse to the appropriate authorities.

Include a description of where the research files will be stored, the duration of storage and security measures used to protect the data. For example: Research records will be stored in a locked office in a locked file cabinet

and will only be accessible to research staff listed on the first page of this consent form. Research data will be destroyed [at least three] years after the end of this study.

If the information to be collected will be stored on any electronic device, the investigator should not only have their devices encrypted, but the subject should also be informed of this process.

If information collected from the subject will be shared indicate with whom it will be shared. If the information is identifiable, please describe the process you will use to protect the research participant's identity. Suggested text for sharing de-identified data: I allow my de-identified data to be shared with other researchers.

If video or audio tapes are used to record information, describe how the recording will be used, who will have access, how long the recording will be stored and when it will be erased. Also state whether or not the participant will be able to review and edit the tape(s) prior to any publication

If your study involves DNA Research, see Supplement Language on the HRPP website.

The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you.

WHAT WILL HAPPEN IF I AM HURT OR INJURED? (Include this section if your study involves more than minimal risk):

Sample Statement -If injury *is not* covered by the study

If any complications arise as a direct result of participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. San Diego State University will not pay for any care, lost wages, or provide other financial compensation [include San Diego State University Foundation if this research is funded]. However, if you feel you have a claim that you wish to file against the State [or the Foundation], please contact Graduate and Research Affairs - Division of Research Administration at (619) 594-6622 to obtain the appropriate claim forms.

Sample Statement - If Injury *is* covered by the study

If you need any treatment or hospitalization as a result of being in this study, all reasonable and customary medical expenses, above what your insurance will cover, will be paid by _____, as long as: you have followed all of the directions of the study investigator, you have notified the investigator immediately of the injury, you have followed medical advice regarding the injury, and you have not deliberately caused the injury.

DO I HAVE TO PARTICIPATE?

You do not have to participate in this research study. If you choose not to participate there is no penalty or loss of benefits to which you are otherwise entitled. Additionally, you may choose to stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

Include a description of the procedures to be followed for the orderly termination of participation by the subject: For example, if data has not been aggregated a statement that the data will be destroyed. In the case where data have been aggregated a statement should be included to indicate data has been aggregated and it is not possible to destroy a participant's data.

Only include if study is under FDA oversight: Under FDA regulations, data collected on subjects up to the time of withdrawal from the clinical investigation must remain in the study database. See 21 CFR 312.62(b) and 812.140(a)(3). If a subject withdraws from a study, removal of data that were already collected may undermine the scientific, and therefore the ethical, integrity of the research." If an investigator conducting research under the provisions of FDA regulations, the investigator is required to inform subjects that their data cannot be destroyed.

If applicable, include a description of the circumstances in which a subject's participation may be terminated by the investigator without regard to the subjects consent.

WILL I BE TOLD ABOUT THE STUDY RESULTS?

Inform subjects whether or not they will be contacted with the results of the original study after it is completed. Suggested wording follows:
We will contact you with results of this study after the study is completed.
State reasons why this disclosure will be made.
OR
We will not contact you with results of this study after this study is completed.

There may be new findings developed during this research which may relate to your willingness to continue to participate in this study. These new findings will be shared with you.

For research genetic research Supplement Language on the HRPP website.

WILL IT COST ME ANYTHING TO PARTICIPATE?

If there are costs associated with participation (e.g., tests, office visits, parking, time, etc.) specify, in detail, the extent of these costs.

WILL I BE PAID FOR MY PARTICIPATION IN THE RESEARCH?

ADD: the amount and schedule of all payments to the subject. If an incentive is offered to participants, describe what is being offered and what is required of the subject to obtain the incentive. If the subject is offered a payment, state the amount, formula for proration should the subject or investigator chooses to discontinue participation, and when payment will occur.

If an incentive is not offered: You will not be paid to participate in this study.

WHAT IF I HAVE QUESTIONS REGARDING THIS STUDY?:

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If you have any questions about the research now, please ask. If you have questions later about the research, you may contact... (Investigator name, work phone with area code)- If you have any questions about your rights as a participant in this study, or in the event of a research related injury, you may contact the Division of Research Affairs at San Diego State University (telephone: 619-594-6622; email: irb@mail.sdsu.edu). At any time during the research you can contact the IRB for questions about research rights, to discuss problems, concerns, or suggestions, or to offer input.

CONSENT TO PARTICIPATE:

The San Diego State University Institutional Review Board has approved this consent form, as signified by the Board's stamp. The consent form must be reviewed annually and expires on the date indicated on the stamp.

Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you have about the study. Your signature also indicates that you agree to be in the study and have been told that you can change your mind and withdraw your consent to participate at any time. The investigator or a member of his/her research team has provided you with a copy of this consent form with information about who to contact in the event you have questions. You have also been given a copy of "The Research Participant's Bill of Rights."

Name of Participant (please print)	Date
Signature of Participant	Date
Signature of Investigator	Date

Note: If this consent document is being developed to obtain parental permission, the signature line should be labeled "Parent(s)/Guardian of Participant(s)." In addition, include a line that would be used by the parent/guardian to indicate the name of the child for whom they are giving permission.

Additionally, this consent document may be used for assent of participants between 14-17 years of age by changing the title from “Informed Consent Form” to “Assent Form”. Please note that when this document is modified to obtain assent of minors between the ages listed above, you are still required to obtain informed consent form the minor participant’s parent(s)/guardian(s).