***IMPORTANT: ALL SECTIONS ARE REQUIRED UNLESS OTHERWISE NOTED. BEFORE FINALIZING & UPLOADING THIS DOCUMENT, REMOVE: THIS SECTION, ALL [RED INSTRUCTIONAL TEXT] AND BLUE EXAMPLES.***

**University of California, Irvine**

**Study Information Sheet**

***[Title of Study]***

**Lead Researcher**

Name and Title

Department

Telephone number and e-mail address

**Faculty Sponsor** *[If not applicable, please remove]*

Name and Title

Department

Telephone number and e-mail address

**In the instance of parental permission, “You” refers to “Your child.”** *[If not applicable, please remove]*

* Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.
* You are being asked to participate in a research study. Participation in this study is voluntary. You may choose to skip a question or a study procedure. You may refuse to participate or discontinue your involvement at any time without penalty or loss of benefits. You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**.
* You are being asked to participate in a research study *[Explain the purpose of the research] Examples: to explore attitudes of first-generation Americans regarding education; to understand how social support influences mental health*
* You are eligible to participate in this study if you *[List all eligibility criterion] Examples: are at least 18 years of age or older; are right-handed; live in Orange County*
* The research procedures involve *[Include the type of procedures, how long they will take, if they will be audio or video taped, and where they will take place] Example: an audio-taped interview that will last approximately 30-45 minutes at a location convenient for you.*  The research procedures will last about [*XX minutes or hours*].
* Possible risks/discomforts associated with the study are *[List all potential risks/discomforts]* *Examples: an invasion of your privacy; a potential for a breach of confidentiality; embarrassment/social stigma; psychological distress*
* There are no direct benefits from participation in the study. However, this study may explain *[Include the benefit society may get as a result of this research being conducted]*
* *[If no alternatives]* There are no alternative procedures available. The only alternative is not to participate in this study.

*[If subjects will be compensated with extra course credit*] The course instructor offering extra course credit for participation in research must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research.

* *[If the research involves using Amazon Mechanical Turk (AMT) include the following language]* The data you provide may be collected and used by Amazon as per its privacy agreement.  This survey contains a number of checks to make sure that participants are finishing the tasks honestly and completely. As long as you read the instructions and complete the tasks, your HIT will be approved. If you fail these checks, your HIT will be rejected. This research is for residents of the United States over the age of 18; if you are not a resident of the United States and/or under the age of 18, please do not complete this survey.
* *[If subjects will not be compensated]* You will not be compensated for your participation in this research study.

*[If subjects will be compensated through the social science lab]* You will receive extra course credit for an eligible course through the UCI Social Sciences human subjects’ pool.You will receive a ½ unit of course credit for each ½ hour of participation in this study. Total amount of credit you may earn for this study is *[Enter total # of units]*. The course instructor offering extra course credit for participation in research must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the amount of extra credit that can be earned through participation in research.

*[If subjects will be compensated for one session]* You will receive *[Enter type of compensation and amount/value]* for your participation in this study. *Example: a $5 gift card to a local merchant*

*[If subjects will be compensated for multiple sessions]* You will receive *[Enter type of compensation and amount/value]* after each study visit. There are *[Enter # of study sessions]* sessions. Total compensation for participation in this study is *[Enter total compensation for completion of the study]*. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

*[If subjects will receive payments in excess of $600 per calendar year, the Internal Revenue Service (IRS) requires that UCI report payments in excess of $600 per calendar year on Form 1099-Misc]* Since you may receive compensation in excess of $600 per calendar year, your name and social security number will be collected and released to the Office of Accounting to process the Form 1099-Misc for Internal Revenue Service (IRS) tax reporting purposes.

*[If subject compensation is processed through UCI Accounting]*Personal information about you, including your name, address, and social security number, will be released to the Accounting Office for the purpose of payment.

* *[Keep all statements that apply to this study and remove/revise as applicable]* There is no cost to you for participation in this study. However there may be out-of-pocket expenses such as parking and transportation fees.
* All research data collected will be stored securely and confidentially *[State how and where. If audio tapes, video tapes, or pictures will be used, state if and when they will be transcribed and destroyed. If participant names will be published, state so]*
* The research team, authorized UCI personnel, *the study sponsor* *[If not applicable, please remove]*, and regulatory entities, may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

* *Future Research Use* [*Include one of the following statements. If you are unsure if data may be shared, choose Option 1 so you are not prevented from sharing de-identified study data with other researchers in the future]*

*[Option 1:]* Researchers will use your *specimens and* information to conduct this study. Once the study is done using your *specimens and* information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

*[OR]*

*[Option 2*:] Researchers will use your *specimens and* information to conduct this study. *Specimens and* information gathered during this research study will only be used for this study. They will not be shared with other researchers.

* *[*[*For NIH funded research that started or is ongoing on or after 12-13-16, if research is biomedical, behavioral, or clinical in nature and collects identifiable, sensitive information (including biospecimens)*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)*. Also for non-federally funded research, seeking a Certificate of Confidentiality. If not applicable, please remove]*

To help us protect your privacy, *[*we have obtained / are in the process of obtaining*]* a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings 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 disclosed to 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.

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 *[sponsor name]* which is funding this project.  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.

*[If not applicable, please remove]* The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Researchers will voluntarily disclose information to prevent serious harm to you or to someone else including, *[State here the conditions under which voluntary disclosure would be made (e.g., Examples: child abuse, elder abuse, domestic violence or sexual assault). If no voluntary disclosures will be made, the researchers should so state.].*

*[If not applicable, please remove. Required if the researchers intend to disclose information covered by a Certificate, with the consent of the research participant.]* 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].*

* *Data Retention**[Explain how long the research data will be maintained. Choose the longest option that applies and remove the other options.] [NOTE: The following language applies regardless of whether or not HIPAA applies to this research. If research involves HIPAA: Protected Health Information (PHI) must be destroyed at the earliest opportunity, which may be sooner than the 10-year period. Notwithstanding PHI, research records must be retained as follows.]*

*[UC policy]* In accordance with UC Office of the President policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

*[If the research is conducted under an IND or an IDE]* In accordance with UC Office of the President policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement. In addition, this research involves the investigation of [FDA regulated](https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate) products. As such, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per [FDA sponsor requirements.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4)

*[If the research involves a biorepository]* The researchers intend to store your research data and/or biospecimens in a repository indefinitely. The researchers may continue to use and share your information and information obtained from analyses of your biospecimens indefinitely. Also the use and sharing of your identifiable biospecimens will continue until the specimens are gone.

* *[Required if the study involves collection of specimens, choose one of the following statements and remove the other options]*

*[If specimens will be discarded]* Biospecimens (such as blood, tissue, or saliva) obtained for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent.

*[If specimens and / or information derived therefrom will be collected from a research subject and used for research and / or development purposes]* Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

* If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.
* If you have any comments, concerns, or questions regarding the conduct of this research please contact the researchers listed at the top of this form.
* It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study.  You can tell the researcher in person or call him/her at the number listed at the top of this form.
* Please contact the UCI Institutional Review Board by phone, (949) 824-8170, by e-mail at [IRB@research.uci.edu](mailto:IRB@research.uci.edu) or at 160 Aldrich Hall, Irvine, CA 92697-7600 if you are unable to reach the researchers listed at the top of the form and have general questions; have concerns or complaints about the research; have questions about your rights as a research subject; or have general comments or suggestions.

**What is an IRB?**  An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB’s role is to protect the rights and welfare of human subjects involved in research.  The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.