***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**

**CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT**

***[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

**Other Researchers** *[For minimal risk research, this is not required; please remove]*

*[List only those researchers qualified to finalize the informed consent process]*

**STUDY LOCATION(S):**

**STUDY SPONSOR(S):**

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

|  |
| --- |
| **SUMMARY OF KEY INFORMATION:**  **The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.**  ***Participation is Voluntary***  You are being asked to participate in a research study. Participation is completely voluntary. 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.  ***Study Purpose***  *[Include a brief statement (i.e. no more than 3 sentences) of the study purpose]*  The purpose of this research study is to *[Complete this sentence] Examples: to explore attitudes of first-generation Americans regarding education; to understand how social support influences mental health*  ***Study Procedures***  *[Include a brief yet complete summary (i.e., no more than 3 sentences) outlining study procedures. A detailed description will follow below in a subsequent section.]*  *Example: …*completion of a daily diary of your mood for 30 calendar days. We will also ask you to complete a pre and post-survey.  ***Expected Duration***  *[Include a brief statement (i.e. no more than 3 sentences) of the time commitment required]*  Participation will last approximately…      hours/ weeks/ months and will include…       visits.  *Example: …*1 hour per day to complete the daily diary for a total of 30 calendar days. Completion of the pre and post-survey should take 1 hour in total. There will be 2 study visits.  ***Risks of Participation***  *[Include a brief summary of the* ***main risks*** *(i.e., no more than 3 sentences) for participants on this study. A detailed description will follow below in a subsequent section.]*  The more notable risks of participation include…     .  *Example: …*boredom or fatigue in completing the diary each day. When completing the survey, some questions may make you feel upset. Also, should there be a breach in confidentiality of your data, there is a slight risk that your private information could be shared with individuals who are not members of the study team.  ***Benefits to Participants***  *[Include a brief statement (i.e., no more than 3 sentences) of the benefits to the participant]*  *[If direct benefit to the subject is anticipated]* The possible benefits you may experience from the procedures described in this study include *[Complete this sentence – the description of subject benefits should be clear and not overstated] Examples: increase reading comprehension; improved writing skills; learning about ways to improve your memory*  *[If no direct benefit to the subject is anticipated]* You will not directly benefit from participation in this study.  ***Benefits to Others or Society***  *[Include a brief statement (i.e., no more than 3 sentences) of the possible benefits to science or society] Examples: greater understanding of how grassroots organizations contribute to eco-awareness, greater understanding of how stress influences memory*  ***Alternative Procedures or Treatments***  *[Include a brief statement (i.e., no more than 3 sentences) of alternative procedures]*  The known alternative procedures include…     .  *[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. |

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?** *[Required if the number of subjects would be important in making a decision to participate in research (e.g. small sample size). If not applicable, please remove.]*

This study will enroll approximately       participants. All study procedures will be done at *. . . [If different procedures will take place at different locations, specify accordingly]*.

**AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?**

You must meet the following requirements to be in the study: *[List any specific inclusion or exclusion criteria] Examples: 18 years of age or older; live in Orange County, are right-handed.*

**WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY AND HOW LONG WILL THEY TAKE?**

1. *[Explain the research procedures in chronological order. Include the expected duration of each interview or procedure. If the study involves multiple components (i.e., surveys, focus groups, observations, semi-structured interviews, accessing records, the collection of medical information or biospecimens), or multiple cohorts who will participate in different study procedures (i.e. parents, teachers, children, etc.) it is* ***strongly recommended*** *that you use headings or tables to delineate between different study components and cohorts****.***
2. Participation in the study will include about *[XX visits, interviews, etc.]* and take a total of about *[XX hours]* over a period of *[XX days/weeks].*

**RETURN OF RESULTS** *[Required IF, the study will produce clinically relevant research results. If not applicable, please remove.]*

*[Explain the possibility that subjects may or may not receive research results. This section is meant to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.] Example: You will / will not be provided any clinically relevant information that may pertain to your health.*

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS RELATED TO THE STUDY?

*[For minimal risk studies]* There are no known harms or discomforts associated with this study beyond those encountered in normal daily life. The possible risks and/or discomforts associated with the procedures described in this study include: *[Categorize the risks by severity and include the likelihood of the risk/discomfort occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical]*

*Examples of risks/discomforts – [Keep all statements that apply to this study and remove/revise as applicable]: Examples: anxiety, embarrassment, social stigma (shame or disgrace); and invasion of privacy, a potential for a breach of confidentiality. Other statements:*

*[For greater than minimal risk studies]* The possible risks and/or discomforts associated with the procedures described in this study include: *[Categorize the risks by likelihood and severity of the risk occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical.]*

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

*[Keep all statements that apply to this study and remove/revise as applicable]*

***Compensation*** *[Keep all statements that apply to this study and remove/revise as applicable]*

*[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 is *[Enter total # of units]*.

*[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, or: you will be entered into a raffle to win 1 of 10 Amazon gift cards worth $100; chances of winning are approximately 1 in 100.*

*[If subjects will be compensated for multiple sessions]* You will receive *[Enter type of compensation and amount/value]* for each [study component, such as a survey, experiment, or focus group] you complete. There are *[Enter # and type of study components]*. 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.

***Reimbursement***

*[If reimbursement will be provided]* You will be refunded for the following expenses that you incur *[Complete this sentence] Examples: parking fees, transportation fees*

*[If no reimbursement will be provided]* You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

*Costs [Choose one of the following statements and remove the other option]*

You will be responsible for the following costs: *[Complete this sentence]*

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.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY? *[This statement is required for all Full Committee research studies.* ***Note: This statement cannot be altered.*** *If not applicable, please remove.]*

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.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor *[sponsor name]*, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury.  For more information about this, you may call the UCI Human Research Protections unit at (949) 824-8170 or by e-mail at [IRB@research.uci.edu](mailto:IRB@research.uci.edu)

**WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?** *[Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject’s withdrawal from the study. If not applicable, please remove.]*

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**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

If you withdraw or are removed from the study, the researcher may ask you to *[Complete this sentence] Examples: return for a final visit or evaluation; if you are interested in continuing long-term follow-up procedures; complete an exit telephone interview.*

*[Include the following statements to Inform Subjects of Their Rights Related to Data Retention. If not applicable, please remove.]*

*[When research is not subject to HIPAA regulations]* If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

*[When research is subject to the HIPAA Privacy rule]* If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

*[When private identifiable information or biospecimens are maintained for future research]* You are free to withdraw your consent to use your identifiable private information and biospecimen for future research at any time however there are some limitations. If you withdraw your consent, the researchers will not use your information or biospecimens in future research studies. However, any of your information or biospecimens already being used in a research study that began before your request to withdraw will continue to be used for that specific study. Also if information and biospecimens have already been provided to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

**HOW WILL MY PERSONAL INFORMATION BE KEPT?**

***Subject Identifiable Data***

*[Explain whether subject identifiers will be linked to the research data. Choose one of the following statements and remove the other options.]*

Identifiable information collected about you will be removed at the end of data collection.

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. *[Explain why personal identifiers will be retained.]*

Identifiable information collected about you will be kept with the research data. *[Explain why personal identifiers will be retained.]*

***Data Storage*** *[Describe how the data will be maintained. Keep and revise all statements that apply and remove the other options.]*

Research data will be maintained in paper format in a secure location at UCI.

Research data will be stored electronically on a laptop computer in an encrypted file *[and* *is password protected].*

Research data will be stored electronically on a secure [*computer or network*] in an encrypted file *[with password protection].*

The *[audio/video recordings]* that can identify youwill also be stored in a secure location; then transcribed and erased as soon as possible.

The *[audio/video recordings]* will also be stored in a secure location; then transcribed and erased at the end of the study.

The *[audio/video recordings]* will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

***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.

**WHO WILL HAVE ACCESS TO MY STUDY DATA?**

The research team, authorized UCI personnel, the study sponsor *[If applicable; otherwise please remove]*, and regulatory entities such as the Office of Human Research Protections (OHRP), 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.

***ClinicalTrials.gov*** *[Include these statements if this study is a clinical trial and will be registered on clinicaltrials.gov]* ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law.  This Web site will not include information that can identify you.  At most, the Web site will include a summary of the results. You can search this Web site at any time.

***Certificate of Confidentiality*** *[*[*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 or has obtained a Certificate of Confidentiality from the NIH, FDA or another federal entity. 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) / FDA / <specify other federal entity>. 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 or for information that must be disclosed in order to meet the requirements of the federal Food and Drug 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.

*[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 – this language is if the researcher 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].*

***Medical Care***

*[Required if the researcher is utilizing Oncore]*

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your records. If necessary for your care, this information will be provided to you or your physician.

**ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?**

***Investigator Financial Conflict of Interest*** *[Required IF there could be the appearance of a conflict of interest. If not applicable, please remove.]*

No one on the study team has a disclosable financial interest related to this research project.

*[If a study team member has a disclosable financial interest the UCI Conflict of Interest Oversight Committee will develop specific language detailing the financial interest.]*

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

*[If biospecimens 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 biospecimens 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.

***Future Contact*** *[Required if researchers intend to contact participants for future research. If not applicable, please remove.]*

The study team would like your permission to contact you for future research. Please initial your level of permission below:

\_\_\_\_\_\_ Yes, UCI researchers may contact me in the future to ask me to take part in other research studies.

\_\_\_\_\_\_ No, UCI researchers may **not** contact me in the future to ask me to take part in other research studies.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

Please contact 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.

**HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?**

You should not sign this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form to keep. **Participation in this study is voluntary.**  You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

*[If participants will be asked to indicate their willingness to have their interview or research activities recorded: If not applicable, please remove.]*

\_\_\_\_\_ Yes, I agree to allow the research team to audio record my interview.

\_\_\_\_\_ No, I do not agree to allow the research team to audio record my interview.

\_\_\_\_\_ Yes, I agree to allow the research team to video record (*the study procedures/my interview/etc.*)

\_\_\_\_\_ No, I do not agree to allow the research team to video record (*the study procedures/my interview, etc.).*

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

***I agree to participate in the study.***

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**Subject Signature Date**

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**Printed Name of Subject**

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***Legally Authorized Representative/Guardian Signature Date***

*­­­­­­­­­­­­­­­(Remove all LAR signature lines if Surrogate Consent / Parent Permission is not applicable)*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*­­­­­­­­­­­­­­­****Printed Name of Legally Authorized Representative/Guardian Relationship to Subject***

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***Legally Authorized Representative/Guardian Signature Date***

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*­­­­­­­­­­­­­­­****Printed Name of Legally Authorized Representative/Guardian Relationship to Subject***

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**Signature of Person Obtaining Informed Consent Date**

*(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)*

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­­­­­­­­­­­­­­­ **Printed Name of Person Obtaining Informed Consent**