Official Title of the Study:	Ethnic Influences on Stress, Energy Balance and Obesity in Adolescents
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UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Ethnic Influences on Stress, Energy Balance and Obesity in Adolescents

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 below will be available to answer your questions.

LEAD RESEARCHER:
Uma Rao, M.D. 949-824-8040
Department of Psychiatry and Human Behavior, UCI
Child & Adolescent Psychiatry, CHOC
UCI 24 Hour Telephone number: 714-456-7890
CHOC 24 Hour Telephone number: 714-602-0442

STUDY LOCATIONS:
University of California at Irvine (UCI), Irvine, CA
949-824-4559
CHOC Children's Hospital, Orange, CA
714-509-4077
Other Agencies Affiliated with UCI & Public Places

STUDY SPONSOR: National Institutes of Health

WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of the study is to identify factors that are associated with weight problems in African-American (Black), Hispanics and Caucasian (White) adolescent females.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

This study will enroll approximately 300 adolescent females to participate in this study. The study procedures will be done at UCI, CHOC or other agencies affiliated with UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements

You and your child can participate in this study if your child is between 13 and 17 years of age, inclusive, female, and African- American, Hispanic or Caucasian.

Exclusion Requirements

You and your child cannot participate in this study if your child has a body mass index (calculated by weight and height) below the normal range, is trying to lose weight, on medications that affect appetite, or if your child is pregnant

HOW LONG WILL THE STUDY GO ON?

The study consists of four separate assessments, totaling about 17-20 hours of your child's time. Each assessment will include specific assessments that are detailed below. The total duration of the study is about 2-3 weeks.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?

Assessment 1 (3-5 hours): This involves coming to UCI, CHOC, your place of residence or another affiliated agency, if this location is more convenient for you.

Interviews: During the visit, we will interview you and your child. The interview topics include questions about your family background and any health problems, and traumatic and stressful events your child might have experienced. These topics may be sensitive for you or your child. You and your child may choose to skip any questions you do not want to answer. We may audiotape the interview with a digital recorder. We will tell you and your child when we are taping. You and your child may decide at any time that you do not want your responses to be taped. Audiotapes of the interviews will not include your name or your child's name or any information that would allow someone to identify who you or your child is. These tapes will be used to assure that our research staff asks the right questions and for training new staff members. The recordings will be stored in a secure locked cabinet in the lead researcher's laboratory and only research staff will have access to them.

After this interview, based on the study criteria, you and your child may be withdrawn from the study. If you both are withdrawn from the study, we will pay you and your child for your time for this interview.

If we find that your child is experiencing physical, sexual or emotional abuse or could be in possible danger, we have to report it to the proper authorities to keep your child safe. Before we make the report, we will discuss this with you and your child.

Questionnaires: We will also ask you and your child to complete some questionnaires. You will complete information about any stressful experiences your family may be experiencing and information about your childhood and your child's experiences and any mental health problems your child may be experiencing. You will also complete information about your own stressful experiences, your relationship with your child, and your relationships with others. Your child will complete information about her puberty, mental health problems, childhood experiences, food preferences and eating patterns, stressful experiences and how she copes with these experiences, and social support. If she is unable to complete all the questionnaires during this session, she can complete them at home and then return them by mail in a self-addressed envelope or bring them to the next visit.

Discussion Task: You and your child may participate in a conversation about stressful events your child has experienced. During the conversation, you and your child will wear a small monitor on your wrist and fingers. This monitor measures how your body is responding (your heartrate and pulse, how much sweat you are producing). You and your child will also complete brief questionnaires about how you are feeling and what you are thinking before and after the discussion. You will complete a speaking task about your child before the discussion. We will video record the discussion and audio record the speaking task. Discussion recordings are stored digitally on a secure network drive. This task is optional. In addition, if more than one child from the same family is participating in the study, the Discussion Task will be collected by one child only. As to who will complete the Discussion task will be decided by chance, like a flip of a coin. If you and your child refuse to participate in this task, you still will be eligible to participate in other parts of the study. Also, you and your child (both) must speak English to participate in the discussion task.

Instructions: You and your child will receive detailed instructions on the assessments that will occur during Visit 2, which will take place at your home next week. Your child also will be fitted with a monitor on the wrist (watch-like) to measure daily activity levels over the next week.

After collecting visit one items, we may ask your child to re-do visit one assessments if we find the results are not valid.

Assessment 2 (3-4 hours over a one-week period): This assessment will be at your home

Diet Information: One of the research staff will contact your child by telephone on three separate evenings and will ask her to provide information on what she ate in the previous 24 hours. Each interview should take about 30 minutes.

Physical Activity and Sleep: During the week, your child's physical activity levels and sleep will be measured by a watch-like monitor, called the Actigraph, worn on the wrist continuously for a week. You will receive no payment of any kind until the Actigraph watch that is loaned to you is returned. The Actigraph watch is the research property of UCI and obtained through federal funds. It has no value to outsiders but this device is very valuable to UCI because of the important research data. If you choose to discontinue your participation prior to completing the full study, you are still responsible for returning the Actigraph watch promptly. If you do not return the Actigraph watch by the specified return date, you may be held financially responsible for its replacement cost ($300). If the Actigraph is not returned, you will not be compensated for the remaining visits, and you will not pay for the replacement cost.

Saliva Samples: On two consecutive days during the same week, your child will be asked to provide 5 saliva (spit) samples each day. Detailed instructions will be given during Visit 1 on how to collect these saliva samples. Also, your child will be provided with a container along with the devices to collect the saliva samples. The saliva samples will be collected at the following times each of these two days: when your child first wakes up, 30 minutes after she wakes up, before lunch, in the afternoon around 4:00 pm, and before she goes to bed. Collecting each saliva sample will take about 5-10 minutes. Saliva samples must be stored in provided plastic bags in a freezer until you or your child bring them when you come for Visit 3.

Questionnaire: Your child also will complete a questionnaire on daily stressful experiences on the days she completes the diet information and saliva samples (total 5 times).

After collecting visit two items, we may ask your child to re-do visit two assessments if we find the results are not valid.

Assessment 3 is a two-part visit (5-6 hours per visit): This involves coming to the Institute of Clinical and Translational Sciences (ICTS) at the UC Irvine campus or the UC Irvine medical center

Assessment 3 will consist of two separate visits and will be conducted at UCI or its affiliated centers. Directions will be provided to you and your child on how to get to the study site. These two visits will be separated by 5 to 31 days in between. For each site visit, your child should not eat anything after 10 pm the night before, and she should come to the study site in a fasting state.

Blood Sample: In only one of the assessments, a blood sample (approximately 50 ml) will be collected. This blood sample will be used to measure hormones that relate to stress, appetite regulation and metabolism. The blood draw will only occur once during the duration of the study.

Urine Sample: In only one of the assessments, a urine sample will be collected. This urine sample will be used to measure various conditions related to your child's health.

DXA Scan: In one of the assessments, your child will have a body scan that is somewhat like an X-ray. This scan is solely for the purpose of this research and your child would not have this scan if you decide not to participate in this research study. A DXA scan uses radiation to create pictures of the structures inside the body. Your child will complete a routine questionnaire regarding her menstrual cycle and possibility of pregnancy prior to the DXA scan to avoid possible harm to an unborn baby.

The total radiation dose that you will receive from 1 scan of this type is about 0.7-1.5 millirem. A millirem is a unit used to quantify radiation dose. Typically, persons in the U.S. receive a radiation dose of about 310 millirem per year (or 0.85 millirem per day) from natural sources of radiation, including from the sun, air, water and soils. Therefore, your child's total radiation dose will be about the same as 1-2 days of natural background radiation.

There are no known health effects associated with this amount of radiation exposure, and no radiation remains in the body after the scan. If you are especially concerned about radiation exposure, you should discuss this with the researcher listed at the top of this form.

Your child will be asked to lie flat on a table while a machine scanner moves up and down her body, without touching, and takes pictures. These pictures provide information on the amount of muscles, bones and fat in a person's body. This test will last about 15 to 20 minutes.

Food Experiments: Your child will participate in two types of food experiments, one at each visit. In one visit, the food experiment will be conducted after she is well relaxed. In the other visit, the food experiment will be conducted after she performs an evaluation task in front of an audience. This task is similar to what most teens experience in school, but it may cause anxiety. The order of these two food experiments (which one will occur first) is based on a random basis (like a coin toss).

After the blood sample and DXA scan, your child will be given breakfast. Then, she will be asked to relax for about two and three quarters (~2.75) hours during which she may read or watch TV programs that the research staff approve. Then, she will be asked to provide two saliva samples, 15 minutes apart, for measuring stress and appetite regulating hormones. Also, she will be asked to rate on how she is feeling before collecting the saliva samples.

For the relaxation food experiment, your child will watch a short nature movie after collecting the saliva samples. For the evaluation condition, she will be given instructions and then asked to perform in front of an audience. This task is similar to tasks that youth normally perform in the classroom. Each of these tasks (movie or evaluation task) will last about 15 minutes. Your child again will be asked to repeat the ratings on feelings and saliva samples after 1 minute, 10 minutes, 20 minutes and 30 minutes (4 samples) after completing these tasks. Then, she will be given buffet lunch and will be discharged from the study site.

Additional Procedures:
Blood spot: Your child will be asked to provide a few drops of blood. This sample will be used to examine biological markers for inflammation. If the first attempt is unsuccessful (i.e. your child's finger does not produce enough blood), your child will be asked if she is willing to try again.

Weight, Height and Waist Measurements: We will take your child's weight, height and waist measurements.

Hair Sample: One of the research staff will cut two separate bundles of hair from your child. A total number of ~ 60 strands of hair will be cut close to her scalp from two locations at the back of her head (most people shed between 50-100 strands per day naturally). The hair sample will be used to measure stress hormone levels. Also, she will be asked questions about hair washing frequency, hair treatment and hair color.

Visits may be combined, or assessments may be completed at the next study visit based on your preference, time constraints, and staff availability. Additionally, some interview and questionnaire measures may be completed by phone, mail or online if they are not able to completed at a study visit.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

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:

Questionnaires and Interviews: Some people feel uncomfortable reporting about personal information. For example, you or your child may experience some emotional discomfort in answering questions about your family's and child's problems and past traumatic experiences. If you or your child feel(s) uncomfortable while completing the interview or any of the questionnaires, then you both are free to choose not to answer those questions. Also, if you wish to stop at any time, you can do so by telling the research staff person.

However, you might not be able to continue in the study if you stop or do not answer certain questions.

Hair Sample: Collection of the hair samples may cause some physical discomfort if your child's hair is pulled while cutting it. Also, it is possible that she may experience discomfort with the idea of someone cutting hair from the back of her head. We will try to make sure that the sample locations are well-hidden.

Dietary information and activity level monitoring: These have no known risks although it may be inconvenient for you or your child to provide the information at specified times and for her to wear the activity monitor. Wearing the Actigraph watch band can potentially cause a skin reaction so taking off the watch for a few hours is suggested.

Saliva and urine collection: These are not associated with any known risks. However, it might be inconvenient for your child to provide the saliva samples at specified times.

Monitoring heart rate and sweat gland activity: These have no known risks.

Blood sampling: Removing blood from a vein can cause pain, redness, soreness, bruising, or infection at the site. Rarely, some people faint. A numbing cream such as ELA-Max may be used so that your child will not feel the needle stick as much. The numbing cream may make your child's skin or the area have a change in skin color, but this is rare. A trained staff person will perform the blood draw.

Blood spot: Removing blood by a lancet (blade) may cause temporary pain, bruising and bleeding. In rare occasions it may cause swelling, dizziness, fainting or infection.

DXA Scan: Having a DXA scan exposes your child to radiation. The amount of radiation she will receive is equal to 1-2 days of radiation from natural surroundings. Because this scan uses radiation, your child will complete a questionnaire regarding her menstrual cycle and possibility of pregnancy. If the research team suspects she is pregnant, she will be withdrawn from the study.

Incidental findings: There could be some clinically concerning abnormality from the DXA scan. If there is such finding, it will be sent for further evaluation.

Evaluation Task: The evaluation task in front of the audience might cause discomfort or anxiety. Your child can stop the procedure any time if she chooses not to continue with the task.

Fasting: Your child will have to fast overnight before the food experiments. She can stop the study if she finds this uncomfortable.

Also, she cannot request for specific foods for the food experiments. The meals will contain a wide variety of foods that she can select from. If she is allergic to certain foods, she may not participate.

Visit scheduling: If your child is in this study, you and she may have some hassles or discomforts. It may

be hard for you to set a time when you both can take part in this study. You may stop participating in this study at any time

Confidentiality: There is a possible risk that your or your child's confidentiality or privacy could be breached. This would mean that someone other than the research team or our collaborators may find out that your child was in the research or may see your or your child's answers or your child's medical information. However, we will take every precaution to make sure that this does not happen.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

All the assessments are for research purposes only. You and your child will not receive any benefit from participating in this study.

Benefits to Others or Society

There is a possible benefit from the study to society. This study will attempt to identify the biological, behavioral and social mechanisms underlying ethnic/racial differences in obesity-related factors between black and white adolescent females. A better understanding of the contributing factors will be helpful in developing more "personalized", ethnically-sensitive programs to reduce such weight problems in youth.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You and your child together can earn up to a total of $420 for completing all aspects of the study: (1a) for completing Visit 1 interviews, questionnaire, body measurement, and hair sample tasks, you will receive $25 and your child will receive $50 ($25 for hair sample and $25 for interviews and questionnaires); (1b) for completing the Visit 1 discussion task, you will receive an additional $15 and your child will receive an additional $15; (1c) your child will be compensated an additional $15 for providing the dried blood spots; (2) for completing Visit 2 and after a team member has checked for completeness of visit two items, your child will receive$25 for valid Actigraphy data, $25 for valid saliva collection time points, $25 for completing three food recalls and a $25 bonus for completing all items; (3) for completing Visit 3 and Visit 4 your child will receive $200 ($75 per food experiment session [$150 for 2 sessions], $25 for blood sample collection, and $25 for DXA scan). If your child completes all the assessments in the study, she will receive a prize (such as a toy, water bottle, t-shirt, etc.) valued at $15 or less.

If you or your child withdraws from the study before completing all the assessments for any particular visit, there will be no payment. However, if the researchers decide to withdraw you/your child from the study, you will be paid for that visit even if all the assessments are not completed.

Reimbursement

Travel costs will be reimbursed to you at a rate of $0.40 (40 cents) per mile up to a maximum of $40 for a round trip visit. The payment will be rounded off to the nearest dollar. If the calculation is $0.50 and under, the payment will be rounded to the previous dollar. If the calculation is $0.51 and over, the payment will be rounded up to the next dollar. For example, if the payment is $9.50 it will be rounded to $9.00 and if the payment is $9.51 it will be rounded to $10.00. If you don't have a car, we will provide bus passes or a taxi service, if necessary. We will also serve you and your child snacks/meals when the study visits are long.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you or your child for participation in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you (your child) 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 (your child) 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, 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 UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You and your child 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**. Your child may be withdrawn from the study for any reason, including determination that your child does not meet full criteria for participation in the study, concern about your child's safety, concern about your child's ability to complete any of the visits, concern about your truthfulness or your child's truthfulness on any of the interview or questionnaire items, or missing one or more study visits.

If you experience any of the side effects listed above, if your (child's) health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

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.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?

Subject Identifiable Data
All 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.

Data Storage
Research data will be stored electronically on a secure network server in an encrypted file with password protection.

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

Data Retention.
The researchers intend to keep the research data for approximately 6 years.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, the study sponsor, off-site research collaborators and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information

about you.

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.

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 or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality

To help us protect your privacy, the sponsor (National Institutes of Health) has a Certificate of Confidentiality. With this Certificate, the researchers cannot be forced to disclose information that may identify you or your child, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you or your child, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet federal requirements.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself/your child or your (child's) involvement in this research. If an insurer, employer, or other person obtains your written permission to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you or your child as a participant in the research project under the following circumstances: the Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of suspected child abuse and neglect, or concern that you or your child may hurt yourselves or others.

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

Use of Specimens

Any specimen(s) (e.g., blood, hair, saliva) obtained for this study will become the property of UCI. Once your child provides the specimens, you will not have access to them. UCI may share your child's specimens in the future with other researchers or outside institutions. Information that identifies your child will not be shared with anyone outside of UCI. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by UCI. You will not receive any money or other benefits derived from any commercial products or other products that may be developed from the use of your child's specimens.

Any specimens (e.g., urine, hair or blood) obtained for routine labs will be kept after the intended use in the event new techniques are developed that could provide useful information for future patients.

Optional Consent for Storage of Blood Sample for Future Research

With your permission, we would like to store your child's blood sample indefinitely for use in future research. The blood sample will not contain any information that identifies your child and will be used for research purposes only. You do not have to agree to this in order to be in the study, and your decision will not affect the care you receive from the study doctors or your clinical care at UCI or CHOC.

YES	NO

Initials

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

Optional Consent for Future Contact and Sharing Data
We would like to share your and your child's data with our other studies that you and your child may qualify or be eligible for and/or agree to participate. Sharing your and your child's data with other studies is entirely voluntary and optional. You and your child will still be able to participate in this study without having to agree to future contact from other studies or to share data with those studies.

If you and your child are interested, then we will share some of your and your child's identifiable information with other researchers at UC Irvine who may be performing similar research so that they may check the information against their eligibility criteria. If you and your child are a good match, then they may contact you to tell you and your child more about their research. Also, if they have same assessments, they will use the collected information so that you and your child don't have to repeat the same assessments. These researchers will follow the rules for keeping you and your child's information private, and you and your child can refuse to participate in these studies without any penalties.

UCI researchers may contact me and my child in the future to ask me to take part in other research studies, and share our data with other researchers. Please mark and initial your answer.

YES	NO

Initials

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.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

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 and date 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, and the attached "Experimental Subject's Bill of Rights" 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, 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.

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.

Note: If the research described in this form involves your (child's) protected health information (PHI), you will be asked to sign a separate UC HIPAA Research Authorization form for the use of your (child's) PHI.

I agree to participate in the study, and I agree for my child to participate in this study.

_____

Printed Name of Child

_____ _____

Printed Name of Parent Subject **Date**

_____

Subject (Participating Adult) Signature

_____ _____

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

_____ _____

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

_____ _____

Signature of Person Obtaining Informed Consent **Date**

_____

Printed Name of Person Obtaining Informed Consent

This section to be completed ONLY if child participant turns 18 before completing study protocol:

_____ _____

Signature of Adult Child Participant (now over 18) **Date**

A witness signature is required on this consent form only if: ***(Researchers: check which one applies)***

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation 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 right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.